EXHIBIT 4

IN THE UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF MICHIGAN

SOUTHERN DIVISION

TRUTEK CORP.,
Plaintiff,

v.

BlueWillow Biologics, Inc.
ROBIN ROE 1 through 10, gender neutral fictitious names, and ABC CORPORATION 1 through 10 (fictitious names).

Defendants.

CIVIL ACTION No. 2:21-cv-10312-SJM-RSW

PLAINTIFF'S EXPERT REPORT OF AMIRALI Y. HAIDRI, ESQ. RESPONSIVE TO AND IN REBUTTAL OF DEFENDANT'S OPENING EXPERT REPORT OF MANSOOR M. AMIJI

RESPONSIVE EXPERT REPORT OF AMIRALI Y. HAIDRI, ESQ.

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D Portion from a Clinical Study Report dated March 7, 2012, titled, "A Multi-Center Study to Determine The Safety and Efficacy of Trutek's 'Multi Acting Particle Blocker (MAPB)' as a Preventive Treatment for Cold and Flu."

E USPTO Office Action dated August 25, 2011 concerning U.S. Patent Application Serial No. 12/467,271 (Wahi) constituting a non-final rejection of all claims for lack of enablement.

F Claims 1 and 2 of U.S. Patent Application Serial No. 12/467,271 (Wahi) as originally submitted to the USPTO on May 16, 2009.

G USPTO Office Actgion dated November 9, 2005 concerning U.S.Patent Application Serial No. 10/458,078 (Rolf) constituting a non-final rejection of all claims for obviousness double patenting, lack of enablement, anticipation by and obviousness over the prior art.

H U.S. Patent No. 6,090,403 issued to Block, *et.al.*, on July 18, 2000.

I U.S. Patent No. 6,844,005 issued to Wahi, *et.al.*, on January 18, 2005.

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AMIRALI Y. HAIDRI
CERTIFIED CIVIL TRIAL ATTORNEY
110 Hillside Avenue, Suite 104
Springfield, New Jersey 07081-3007
Tel: (908) 688-8700
Fax: (908) 688-8445
Email: amiraliyhaidri@aol.com

Amirali Y. Haidri 1
Certified by the Supreme Court
of New Jersey as a Civil Trial Attorney

1 Member of the N.J.
and N.Y. bars

New York Office
166 East Park Avenue
Long Beach, NY 11561
(973) 232-6581 Tel
(973) 232-6313 Fax

TERMS OF ENGAGEMENT

TRUTEK Corp.
281 East Main Street
Somerville, NJ 08876

Gentlemen:

You have engaged my services as a technical expert in the matter of Trutek Corp. *v.* BlueWillow Biologics, Inc., currently in litigation in the Eastern District of Michigan, Southern Division, Civil Case No. 2:21-cv-10312-SJM-RSW. You allege that BlueWillow Biologics, Inc. ("BlueWillow") infringed the claims of your U.S. Patent No. 8,163,802 (hereinafter, "the '802 Patent").

I am an attorney licensed to practice in the States of New Jersey and New York, and I am licensed as a patent attorney at the United States Patent and Trademark Office. I obtained my undergraduate degree in chemical engineering in 1971 and a master's degree in organic chemistry in 1983. I have been a practicing patent attorney since 1982. My resume is attached hereto as Exhibit A.

I read and understood the specification and claims of the '802 Patent. I also read and understood the opening expert report by Mansoor M. Amiji on invalidity of the '802 Patent and the accompanying exhibits. My first assigned task is to provide a rebuttal report. You have also requested that I provide testimonial evidence in rebuttal to BlueWillow's allegations of patent invalidity.

My current fee for services is $350 per hour. I will be entitled to receive reimbursement for travel and out-of-pocket expenses related to this engagement.

Amirali Y. Haidri, Esq.

II. FINDINGS AND CONCLUSIONS

Having reviewed BlueWillow's opening expert report by Mansoor M. Amiji (the "Amiji Report") along with its exhibits and other relevant materials, I formed the following opinions:

1) The Amiji Report did not make a clear and convincing showing that claims 1, 2, 6, and 7 are invalid for being directed to ineligible subject matter under 35 U.S.C. § 101.

2) The Amiji Report did not make a clear and convincing showing that claims 1, 2, 6, and 7 are invalid for lack of credible utility.

3) The Amiji Report did not make a clear and convincing showing that claims 1, 2, 6, and 7 are invalid for lack of enablement.

4) The Amiji Report did not make a clear and convincing showing that claims 1, 2, 6, and 7 are invalid for lack of adequate written description.

5) The Amiji Report did not make a clear and convincing showing that claims 1, 2, 6, and 7 are invalid in view of Wahi '488 or in combination with Rolf.

6) The Amiji Report did not make a clear and convincing showing that claims 1, 2, 6, and 7 are invalid in view of Wadstrom alone, or in combination with Rolf.

7) The Amiji Report did not make a clear and convincing showing that claims 1, 2, 6, and 7 are invalid in view of Baker '189 alone or Baker '476 alone, or in combination with Rolf, or Khaled, or Rabe, or Katz, or Wahi '790.

III. RELEVANT PATENT STATUTES

A. 35 U.S.C. § 101 - Inventions Patentable

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The invention must be new and useful. An issued patent is presumed valid, and this includes a presumption of validity. *Structural Rubber Prods. Co. v. Park Rubber Co.,* 749 F.2d 707, 741 (Fed. Cir. 1984).

B. 35 U.S.C. § 102(a) - Conditions for Patentability; Novelty

NOVELTY; PRIOR ART — A person shall be entitled to a patent unless —

(1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention; or

(2) the claimed invention was described in a patent issued under section 151, or in an application for patent published or deemed published under section 122(b), in which the patent or application, as the case may be, names another inventor and was effectively filed before the effective filing date of the claimed invention.

35 U.S.C. 102(a) refers to claim anticipation. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California,* 814 F.2d 628, 631 (Fed. Cir. 1987).

C. 35 U.S.C. § 103 Conditions for patentability; non-obvious subject matter.

A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill

in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

> Obviousness is a legal conclusion. *E.g., Aktiebolaget Karlstads v. United States ITC*, 705 F.2d 1565 (Fed. Cir. 1983). It is a question of law to be determined from the facts. *In re. Geiger,* 815 F.2d 686 (Fed. Cir. 1987); *in re. Blauwe,* 736 F.2d 699 (Fed. Cir. 1984). "Whether an invention would have been obvious in terms of §103 is ultimately a legal judgment, dependent from the factual evidence adduced." *Burlington Indus. Inc. v. Quigg,* 822 F.2d 1581 (Fed. Cir. 1987).

D. 35 U.S.C. § 112 Specification

(a) IN GENERAL.—The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.

> Enablement means that practice of the invention must not require undue experimentation, although reasonable experimentation by a person having ordinary skill in the art is permitted. *White Consol. Indus., Inc. v. Vega Servo-Control, Inc.,* 713 F.2d 788 (Fed. Cir. 1985). The enablement requirement is met if the description enables any mode of making and using the claimed invention. *Engel Indus., Inc. v. Lockformer Co.,* 946 F.2d 1528 (Fed. Cir. 1991). The best mode requirement is a subjective test in that it requires a disclosure only of that which the inventor (not someone else) contemplates as the best way of carrying out the invention at the time. There is no duty for an inventor to disclose details of which he or she was not aware. *Gargoyles, Inc. v. United States,* 113 F.3d 1572 (Fed. Cir. 1997).

(b) CONCLUSION.—The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.

(c) FORM.—A claim may be written in independent or, if the nature of the case admits, in dependent or multiple dependent form.

> (d) REFERENCE IN DEPENDENT FORMS.—Subject to subsection (e), a claim in dependent form shall contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed. A claim in independent form shall be construed to incorporate by reference all the limitations of the claim to which it refers.
>
> (f) ELEMENT IN CLAIM FOR A COMBINATION.—An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

E. 35 U.S.C. § 282(a)

> A patent shall be presumed valid. Each claim of a patent (whether in independent, dependent, or multiple dependent form) shall be presumed valid independently of the validity of other claims; dependent or multiple dependent claims shall be presumed valid even though dependent upon an invalid claim. The burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity.

IV. THE CLEAR AND CONVINCING STANDARD OF PROOF

In *Microsoft Corp. v. i4i Limited Partnership,* 564 U.S. 91 (2011), the U.S. Supreme Court held that 35 U.S.C. § 282 "requires an invalidity defense to be proved by clear and convincing evidence." Such evidence requires a higher standard of proof than proof by a preponderance of the evidence.

"'Clear and convincing evidence' is that weight of proof which produces in mind of trier of fact a firm belief or conviction as to truth of the allegations sought to be established; it is evidence so clear, direct, weighty and convincing as to enable fact-finder to come to clear conviction, without hesitancy, of truth of the precise facts of case." *In re CNC Payroll, Inc.*, 491 B.R. 454, 461 (2013), citing *Shafer v. Army & Air Force Exch. Serv.,* 376 F.3d 386, 396 (5th Cir.2004). See also, *In re JMW Auto Sales*, 494 B.R. 877, 889 (2013).

In the United States Patent and Trademark Office (USPTO), when examining a patent application prior to a patent grant, the lower standard of preponderance of the evidence is used. Patent examiners are intimately familiar with patent law, and they routinely interpret proposed claims in light of the inventor's disclosure. Examination of patent applications is delegated to specific art groups employing examiners that deal only with the subject matter of the particular invention. The examination of patent applications prior to issue is rigorous. However, according to 35 U.S.C. § 282(a), patents once issued are presumed valid. Thus, the decisions of the USPTO leading to a patent grant are given great deference.

An applicant for a patent is required to disclose any information known to him that is material to patentability of his invention. This duty is codified in 37 CFR § 1.56, (*viz.*, Duty to disclose information material to patentability). This regulation applies to "applicants and other individuals substantively involved with the preparation and/or prosecution of the application." The disclosure is accomplished by applicant's submission of an Information Disclosure Statement ("IDS"). MPEP[1] § 609. An applicant "also may want the Office to consider information for a variety of other reasons; e.g., to make sure that the examiner has an opportunity to consider the same information that was considered by these individuals, or by another patent office in a counterpart or related patent application filed in another country." *Id.*

With regard to the present matter concerning the '802 Patent, the applicant submitted an IDS, which is attached hereto as Exhibit B. On August 19, 2011, Examiner Raymond Henley III, considered and initialed all of the prior art references submitted by the applicant. This initialed document is attached hereto as Exhibit C. From that initialed document, it is apparent that Examiner Henley considered the following prior art references:

- US Patent No. 5,468,488 issued to Wahi on November 21, 1995 ("Wahi '488");
- US Patent No. 5,674,481 issued to Wahi on October 7, 1997 ("Wahi '481).
- US Patent No. 6,844,005 issued to Wahi on January 18, 2005 ("Wahi '005").
- US Patent Application Publication No. 2003/0223934 published on December 4, 2003 ("Wahi '934").

[1] The term "MPEP" is an acronym for the Manual of Patent Examining Procedure published by the USPTO and intended to instruct patent examiners how to examine applications for patentability.

The Wahi '005 patent issued from U.S. Patent Application No. 10/082,978, which was filed on February 25, 2002. That application was published by the USPTO as US Patent Application Publication No. 2003/0161790 ("Wahi '790"). The specifications of Wahi '790 and Wahi '005 are identical. Thus, Examiner Henley was aware of the teachings of Wahi '790 during prosecution of the '802 Patent. The Amiji Report cited prior art references Wahi '488, Wahi '481, and Wahi '790 to prove invalidity of claims 1, 2, 6, and 7 of the '802 Patent. These three references must be given special deference because they were considered by the USPTO prior to issuing a Notice of Allowance. Under a clear and convincing standard, it is a finding of fact that should be overturned only upon a finding that no reasonable examiner would have allowed the claims in light of the considered prior art.

In *Microsoft* 564 U.S. 91, the Supreme Court rejected "Microsoft's argument that a preponderance standard must at least apply where the evidence before the fact finder was not before the PTO[2] during the examination process." The Court held that the proof of invalidity must be by a clear and convincing evidentiary standard regardless of whether the USPTO previously considered the evidence of prior art.

[2] The acronym PTO means Patent and Trademark Office. It is an equivalent designation to the acronym USPTO used elsewhere in my report.

V. STANDARDS FOR INQUIRY INTO PATENT INVALIDITY

For an application to issue as a patent, the USPTO must determine that the issued claims meet all of the requirements of 35 U.S.C. §§ 101, 102, 103, and 112. Only where clear and convincing evidence is presented that a claim fails to meet any of these requirements may that claim be deemed invalid.

A. 35 U.S.C. § 101

> *Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.*

35 U.S.C. §101 defines what types of inventions are eligible for patent protection, more commonly referred to as statutory subject matter. The scope of inquiry into the statute is:

- eligible subject matter,
- utility, and
- novelty.

1. Subject Matter Eligibility

Eligible subject matter comprises a process, a machine, a manufactured article, and a composition of matter. A process claim is synonymous with a method claim, which is a series of steps that a person of ordinary skill must perform. A formulation may be both a manufactured article and a composition of matter.

Judicial decisions stated that non-man-made inventions are not patentable. For example, "[t]he laws of nature, physical phenomena, and

abstract ideas have been held not patentable." *Diamond v. Chakrabarty,* 447 U.S. 303, 309 (1980). Thus, Einstein's theory of relativity and Newton's law of gravity are ineligible. *id.* These are "manifestations of ... nature, free to all men and reserved exclusively to none." *Funk Bros. Seed Co. v. Kalo Inoculant Co.,* 333 U.S. 127, 130 (1948).

The first step for the USPTO in examining a patent application is to determine whether the subject matter of the invention is allowed under 35 U.S.C. § 101. MPEP § 2106(I). The examiner researches whether each claim of the invention is directed toward one or more of the four patent-eligible subject matter categories of the statute. *Id.* "If the claimed invention is clearly not within one of the four categories, it is not patent eligible." *Id.*

The second step is to analyze whether the claim wholly embraces "a judicially recognized exception, which includes laws of nature, physical phenomena, and abstract ideas," or whether "it is a particular practical application of a judicial exception." MPEP § 2106(II). "The Supreme Court's precedents provide three specific exceptions to § 101's broad patent-eligibility principles: 'laws of nature, physical phenomena, and abstract ideas.'" *Id.*, citing *Diamond v. Chakrabarty,* 447 U.S. at 309. "While abstract ideas, physical phenomena, and laws of nature are not eligible for patenting, methods and products employing abstract ideas, physical phenomena, and laws of nature to perform a real-world function may well be. In evaluating whether a claim meets the requirements of 35 U.S.C. 101, the claim must be considered as a whole to determine whether it is for a particular application of an abstract idea, physical

phenomena, or law of nature, and not for the abstract idea, physical phenomenon, or law of nature itself." *Id.*, citing *Diamond v. Diehr*, 450 U.S. 175, 188 (1981).

Given that Steps 1 and 2 *supra* are mandatory threshold steps for any examiner to evaluate subject matter eligibility under 35 U.S.C. § 101, under the requirement that the clear and convincing standard must be used to invalidate a claim for ineligible subject matter, a challenger would need to show either that the examiner failed to consider subject matter eligibility or that no reasonable examiner would have allowed a claim that was subject matter ineligible. This is a very high bar.

2. Utility

The starting point for a practical utility analysis is *Brenner v. Manson*, 383 U.S. 519 (1966)[1] Here, the Supreme Court held that, "arguments for and against the patentability of a process which either has no known use or is useful only in the sense that it may be an object of scientific research would apply equally to the patenting of the product produced by the process." *Id.* at 533. Further, the Court stated that a "patent system must be related to the world of commerce rather than to the realm of philosophy." *Id.* at 536.

The C.C.P.A. court held in *In re Chilowsky*, 229 F.2d 457, 462 (C.C.P.A. 1956):

> [*I*]*n the usual case where the mode of operation alleged can be readily understood and conforms to the known laws of physics and chemistry, operativeness is not questioned, and no further evidence is required. On the other hand, if the alleged operation seems clearly to conflict with a recognized scientific principle as, for*

[1] *See also Cross v. Tizuka,* 753 F.2d 1040, 224 USPQ 739, 744 (Fed. Cir. 1985).

> *example, where an applicant purports to have discovered a machine producing perpetual motion, the presumption of inoperativeness is so strong that very clear evidence is required to overcome it. A third type of case . . .* [*is an invention*] *of such a nature that it* [*cannot*] *be tested by any known scientific principles. In such a case . . . it is incumbent on the applicant to demonstrate the workability and utility of the device and make clear the principles on which it operates.*

Thus, there are three categories of evidence that may be inherent or required to justify a utility rejection. MPEP § 2107 provides guidelines for examination of applications for compliance with the utility requirement. Determination of utility is also a threshold step under 35 U.S.C. § 101 that must be performed by a USPTO examiner before dealing with issues relating to novelty or adherence to requirements of 35 U.S.C. § 112. Under the requirement that the clear and convincing standard must be used to invalidate a claim for non-utility, a challenger would need to show either that the examiner failed to consider the utility of the invention or that no reasonable examiner would have allowed a claim that was not useful.

3. Novelty

As discussed *supra*, 35 U.S.C. §101 imposes a third requirement that the invention be new. A determination of novelty is based solely on a review of the prior art. Prior art is information that was available to the public before a date of priority afforded to the patent application. The challenger cannot assert lack of novelty unless based on prior art, and hindsight cannot form a basis for lack of novelty. The requirements of a determination of novelty are set forth in 35 U.S.C.§§ 102 and 103. This subject will be discussed at length *infra*.

B. 35 U.S.C. § 112(a) - The Specification

35 U.S.C. § 112(a) states:

> *The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.*

Section (a) of the statutes sets forth three requirements for a patent application's specification:

- the written description requirement,
- the enablement requirement, and
- the best mode requirement.

Each of these requirements is distinct from the other. The specification may contain a written description that is not enabling. The disclosure may be enabling without describing the invention. The description of the invention may not include the preferred embodiment.

1. The Written Description Requirement

A non-provisional patent application comprises two sections – a specification and claims. The specification discloses the invention to the public. The claims lay out the scope of protection that an applicant seeks for his invention. Although not quite analogous to a contract, a patent document is a *quid pro quo*. In exchange for disclosure of details of the invention and not maintaining it secret, the applicant receives protection against others making,

using or selling what is defined as his scope of protection. The disclosure is separate from the claims. Neither may exist without the other.

The disclosure of the invention is in the form of a written description. The disclosure must be in writing. An audio or video disclosure in not allowed. The written description teaches the reader what the inventor believes his invention to be. Often, a patent application includes drawings that graphically describe the invention, and the written disclosure refers to the drawings. However, drawings are not required. The function of the written description is to explain the invention to the public. It tells the public what the applicant invented in plain language. The public will not understand what the applicant invented unless the inventor describes it in writing. Often a specification will discuss prior art and will explain how the invention overcomes the prior art. But, it is not necessary for the applicant to teach to that degree.

A claim will be rejected under 35 U.S.C. § 112(a) for failing to comply with the written description requirement if the specification fails to describe the claimed invention. Without a written disclosure of the claimed invention, the claim is invalid. However, the written description does not need to be a manufacturing specification.

2. The Enablement Requirement

Enablement relates to the specification teaching a person having ordinary skill in the art how to make and use the invention. First, the invention must be operational. If an invention process comprising a series of steps cannot function as described, then the method claiming that process is not enabled. If a

manufactured article invention does not work, then the claim reciting that article is not enabled. It is possible for an invention to be described adequately, and yet not be enabled. A famous example would be a novel perpetual motion machine. Many inventors filed patent applications describing and claiming perpetual motion devices. However, these are not patent eligible because perpetual motion of a mechanical device defies the laws of physics. A claim to such a device fails the § 112(a) enablement requirement.

Enablement under § 112 is closely related to utility under § 101. An invention that is not enabled is also not useful. However, the converse is not true. It is possible for an invention to be useful, but not enabled.

Second, if the specification does not teach a person having ordinary skill in the art (PHOSITA) how to make and use the invention, there is no enablement. The Federal Circuit held:

> *When rejecting a claim under the enablement requirement of Section 112, the* [*Patent Office*] *bears an initial burden of setting forth a reasonable explanation as to why it believes the scope of protection provided by the claim is not adequately enabled by the description of the invention provided in the specification of the application, this includes, of course, providing sufficient reasons for doubting any assertions in the specification as to the scope of enablement*

In re. Wright, 999 F.2d 1557, 1561 (Fed. Cir. 1993).

Claims must be supported by the written description. When a USPTO examiner rejects a claim under 35 U.S.C. § 112(a) for lack of enablement, that rejection means that the portion of the specification that supports the claim describes an invention that either cannot function as described or that fails to teach the person of ordinary skill how to make and use the invention.

Enablement means that practice of the invention must not require undue experimentation, although reasonable experimentation by a person having ordinary skill in the art is permitted. *White Consol. Indus., Inc. v. Vega Servo-Control, Inc.,* 713 F.2d 788 (Fed. Cir. 1985). The governing term is "undue." A detailed manufacturing specification is not required, nor is there an obligation to teach the prior art or to compare the claimed invention with prior art. The enablement requirement is met if the description enables any mode of making and using the claimed invention. *Engel Indus., Inc. v. Lockformer Co.,* 946 F.2d 1528 (Fed. Cir. 1991).

The enablement requirement is satisfied when the applicant describes an embodiment (or example) of the invention that works and that a person of ordinary skill can make or use without undue experimentation. A single enabled embodiment is the only requirement.

3. The Best Mode Requirement

An inventor must disclose at least one claimed embodiment. In most cases, inventors disclose multiple claimed embodiments. However, one of the disclosed embodiments must address the best way of performing the invention as conceived by the inventor at the time the patent application is filed. This embodiment is known as the best mode. Where multiple embodiments are disclosed, if one of them is the best mode, the inventor need not state which embodiment represents the best mode.

C. 35 U.S.C. § 112 - The Claims

35 U.S.C. § 112(b)

> *The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.*

35 U.S.C. § 112(c)

> *A claim may be written in independent or, if the nature of the case admits, in dependent or multiple dependent form.*

35 U.S.C. § 112(d)

> ***...*** *a claim in dependent form shall contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed. A claim independent form shall be construed to incorporate by reference all the limitations of the claim to which it refers.*

Regardless of what is taught in the specification, the claims set forth the metes and bounds of the protection sought by the applicant for his invention. The claims must have support in the written description. A claim must appear as a single sentence beginning with a capital letter and ending in a period. An independent claim is one that stands alone. A dependent claim is one that references another claim set forth previously. A claim is generally divided into three parts: (1) a preamble, (2) a transitional word, or phrase; (3) a body.

In an independent claim, the preamble typically explains to the reader what type of process, machine, manufacture, or composition of matter is covered by the claim. Often, the preamble will set forth the utility for the claimed invention. Examples are: "a method for ..." doing something or "a chemical composition that ..." does something. Then, the preamble may lay out various nouns that will appear in the body of the claim. The first appearance of a noun

should appear with a preceding modifier either "a" or "an." All subsequent appearances of that noun should appear with a preceding modifier either "the" or "said." Failure to follow this convention renders the claim indefinite.

If the claim defines a process, then it will begin with the words: "a process for ...," or "a method for ...." The body of such a claim will set forth a series of steps with auxiliary verbs in active voice ending in 'ing.' Examples are bringing, holding, evaluating, *etc*. If the claim defines a machine, manufacture, or composition of matter, the body of that claim will set forth a series of structural elements that define the invention.

The transitional word or phrase connects the preamble of the claim to the body. Three such words or phrases are used:

- comprising (or comprised of) - This term means 'including' or 'having," and is open-ended. As an example, the phrase, "comprising A, B, and C," means that the claimed invention must include elements A, B, and C, but it may have additional elements.
- consisting (or consisting of) - This term leads to a body that is closed. As an example, the phrase, "consisting of A, B, and C," means that the claimed invention must include A, B, and C and no more.
- consisting essentially of - This is a hybrid term that is closed for the essential elements, but may have additional non-essential elements.

A dependent claim is one that references another claim. Generally, the reference to the base claim appears in the preamble. Examples are, "the method of claim 4" or the "chemical composition of claim 4." A dependent claim

incorporates its base claim by reference therein. Thus, a dependent claim cannot be read alone. It acts as an appendage to its base claim. As an example, if claim 4 recites, "a device comprising A, B, and C," then elements A, B, and C must be present, but it can include more. If claim 5 recites, "the device of claim 4 further comprising D," then claim 5 must be read where A, B, C, and D are present, but it can include more.

D. Rejections Based On Prior Art

1. Anticipation Based On 35 U.S.C. § 102(a)

35 U.S.C. § 102(a):

> (1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention; or
>
> (2) the claimed invention was described in a patent issued under section 151, or in an application for patent published or deemed published under section 122(b), in which the patent or application, as the case may be, names another inventor and was effectively filed before the effective filing date of the claimed invention.

"35 U.S.C. § 102(a) establishes that a person cannot patent what was already known to others." *Woodland Trust v. Flowertree Nursery Inc.*, 148 F.3d 1368 (Fed Cir. 1998). Section § 102(a) is the first of two statutes that addresses the novelty requirement of 35 U.S.C. § 101. A rejection under § 102(a) may only be based on prior art. The effective filing date of a patent is the date of filing of the earliest application to which priority is claimed. Thus, if the patent issued from a particular patent application, and that application claimed priority to one or

more previously filed patent applications, the filing date of the earliest of those applications represents the effective filing date.

Prior art includes:

- a patent issued earlier than the effective filing date,
- a printed publication available to the public earlier than the effective filing date,
- a process, machine, manufacture, or composition of matter in public use earlier than the effective filing date, or
- a patent application published earlier than the effective filing date.

A claim rejection under 35 U.S.C. § 102(a) will be made if the claim is anticipated by the prior art. As discussed *supra*, the body of a claim consists of one or more elements. Anticipation of a claim under §102(a) is made using a single prior art reference. For there to be anticipation, every element of the claim must be taught in that single prior art reference. If that single prior art reference is silent regarding any element of the claim, a rejection under § 102(a) is inappropriate. "In order to anticipate, a prior art reference must be enabling, thus placing the allegedly disclosed matter in the possession of the public." *Azko N.V. v. United States ITC*, 808 F.2d 1471 (Fed. Cir. 1986).[2]

2. Obviousness Based On 35 U.S.C. § 103

35 U.S.C. § 103:

> *A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.*

[2] *See also Ashland Oil Co v. Delta Resins & Refracs.,Inc.*, 776 F.2d 281 (Fed. Cir. 1985) and *Reading & Bates Constr. Co. v. Baker Energy Res. Corp.*, 748 F.2d 645 (Fed. Cir. 1984).

Obviousness is a legal conclusion. *E.g., Aktiebolaget Karlstads v. United States ITC*, 705 F.2d 1565 (Fed. Cir. 1983). It is a question of law to be determined from the facts. *In re. Geiger,* 815 F.2d 686 (Fed. Cir. 1987); *in re. Blauwe,* 736 F.2d 699 (Fed. Cir. 1984). "Whether an invention would have been obvious in terms of §103 is ultimately a legal judgment, dependent from the factual evidence adduced." *Burlington Indus. Inc. v. Quigg,* 822 F.2d 1581 (Fed. Cir. 1987).

It is difficult to arrive at a determination of obviousness. It must be based upon what a person having ordinary skill in the art would have known as prior art earlier than the effective filing date and the inferences that he would have made based on that knowledge. Use of hindsight is impermissible. If the prior art does not contain or suggest that knowledge, the challenger would be using the invention as a template for its own reconstruction. Even if the prior art was available to that fictitious person at the time, there must be a showing that such a person would have considered a claim obvious over the prior art. If much time passed between the effective filing date and the allegation of obviousness, significant care must be taken to insure that he who alleges obviousness does not use his current knowledge of the art to allege obviousness.

Like all legal conclusions, a determination of obviousness is reached after answers to a series of fact questions. *Graham v. John Deere Co. of Kansas City,* 383 U.S. 1, 17 (1966). "Under s 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved."

Because a person having ordinary skill in the art is aware of the prior art, he can combine prior art references to allege obviousness. All patented inventions consist of a combination of old elements. It is not existence of the old elements themselves in a claimed invention that renders the claim obvious, but rather the uniqueness of how they are combined. For example, persons skilled in the art might be familiar with a gear, a cam, or a shaft. Merely because an invention uses gears, cams, and shafts does not make the invention obvious. In other words, if a claim recites a process or other statutory invention comprising elements A and B, it would be improper to combine a reference comprising A with a reference comprising B without further motivation to make that combination. First, it must be possible to combine the references. If A and B cannot be combined, then their combination cannot render the claimed invention obvious. If either one of the references is not enabled for the A element or the B element, then their combination is unwarranted. A person having ordinary skill would not have combined them to make or use the claimed invention. Second, assuming that references can be combined, their combination must produce a process or other statutory item having all of the elements in the claim. The combination may not be silent regarding any element in the claim. Further, the combined elements must function together to accomplish the claimed invention when considered as a whole.

"[S]eeking to resolve the obviousness question with more uniformity and consistency, the Federal Circuit has employed a “teaching, suggestion, or motivation” (TSM) test, under which a patent claim is only proved obvious if the

prior art, the problem's nature, or the knowledge of a person having ordinary skill in the art reveals some motivation or suggestion to combine the prior art teachings." *KSR Intern. Co. v. Teleflex Inc.*, 550 U.S. 398, 399 (2007). "To determine whether there was an apparent reason to combine the known elements in the way a patent claims, it will often be necessary to look to interrelated teachings of multiple patents; to the effects of demands known to the design community or present in the marketplace; and to the background knowledge possessed by a person having ordinary skill in the art." *Id.* at 401. Further, "[t]o determine whether there was an apparent reason to combine the known elements in the way a patent claims, it will often be necessary to look to interrelated teachings of multiple patents; to the effects of demands known to the design community or present in the marketplace; and to the background knowledge possessed by a person having ordinary skill in the art." *Id.*

a. Secondary Consideration – Commercial Success

Commercial success attributable to the merits of the claimed invention is powerful and persuasive evidence of nonobviousness. Commercial success must be considered before a conclusion on obviousness is reached. *W.L. Gore & Assoc. v. Garlock, Inc.*, 721 F.2d 1540, 1555 (Fed. Cir. 1983). "It is entirely proper, nevertheless, in evaluating nonobviousness, for a court to take into account advantages directly flowing from the invention patented. After all, those advantages are the foundation of that "commercial success" which may be evidence of nonobviousness." *Preemption Devices, Inc. v. Minnesota Min. & Mfg. Co.,* 732 F.2d 903 (Fed. Cir. 1984). Evidence of commercial success even

occurring abroad is relevant (if attributable to the merits of the claimed invention), and it is improper for a court to reject it. *Lindemann Maschinenfabrik v. American Hoist & Derrick Co.,* 730 F.2d 1452, 1461 (Fed. Cir. 1984).

"Objective evidence of nonobviousness including commercial success must be commensurate in scope with the claims." MPEP § 716.03(a)(I) citing *In re Tiffin,* 448 F.2d 791 (C.C.P.A. 1971). "In order to be commensurate in scope with the claims, the commercial success must be due to claimed features, and not due to unclaimed features." *Id.* citing *Joy Technologies Inc. v. Manbeck,* 751 F. Supp. 225, 229, (D.D.C. 1990), *aff'd*, 959 F.2d 226, 228 (Fed. Cir. 1992).

"If a particular range is claimed, applicant does not need to show commercial success at every point in the range, ... and where substantial commercial success is achieved at an apparently typical point within those ranges, and ... operation throughout the claimed ranges approximates that at the particular points involved in the commercial operation, we think the evidence as to commercial success is persuasive." MPEP § 716.03(a)(II) citing *In re. Hollingsworth,* 253 F.2d 238, 240 (C.C.P.A. 1958). See also *Demaco Corp. v. F. Von Langsdorff Licensing Ltd.,* 851 F.2d 1387 (Fed. Cir. 1988).

VI. THE PERSON HAVING ORDINARY SKILL IN THE ART

The person having ordinary skill in the art (hereinafter, the "person of ordinary skill") is key to the §103 statute. It is essential that the nature of the person of ordinary skill be ascertained when deciding whether a claim is obvious. An incorrect determination as to level of skill, or an incorrect finding, may constitute reversible error if it influences the ultimate conclusion on obviousness.

Custom Accessories, Inc. v. Jeffrey-Allen Indus., Inc., 807 F.2d 955 (Fed. Cir. 1986).[3] Care must be taken not to select a person of extraordinary skill. We are presented here with three questions:

1. Who is this person?
2. What is ordinary skill?
3. What does this person of ordinary skill know?

The person of ordinary skill is a hypothetical individual. He is a legal fiction very much like the reasonable person. He is not a genius in the art. Also, he is not an inventor. He is definitely not the inventor of the claimed invention, because the claims are not to be evaluated through the eyes of the inventor. However, he is not an automaton. According to § 112, he is the person who is able to make and use the claimed invention at the earliest filing date without undue experimentation. He is a technician capable of modest experimentation

The level of ordinary skill depends upon the art itself. In some cases, the art is so complex that it would require a researcher with a Ph.D. or a medical degree. In other cases, the art is not complex at all, and would require a competent carpenter to fabricate the claimed invention.

However, this fictitious person of ordinary skill not only has the skill necessary for him to make and use the invention without hindsight, but he also has knowledge of the entire prior art repository in his art and the analogous art. Probative factors are his educational background, his history of employment, the types of problems encountered in the art, the rapidity in which innovations are made, and the sophistication of the technology.

[3] *See also Kloster Speedsteel AB v. Crucible, Inc.,* 793 F.2d 1565 (Fed. Cir. 1986).

A. Nature of the Art

In Paragraph 28 on Page 13 of the Amiji Report, the author states, "I understand that Trutek's products are considered cosmetics given that they did not go through the Federal Drug Administration drug approval process." To that end, he presents as a reference the entire Handbook of Cosmetic Science and Technology as an exhibit stating that it is a leading textbook that discusses the various excipients that are disclosed in the '802 Patent.

In Paragraph 68 on Page 28 of the Amiji Report, the author states:

> *I came to the conclusion that the characteristics of a person of ordinary skill in the art of the '802 Patent would be someone who had at least an M.S. degree in chemical engineering, pharmaceutical sciences, or a related field (or the equivalent) with several years of experience with pharmaceutical formulation. Also, a person of ordinary skill in the art may have worked as part of a multidisciplinary team—including a chemical engineer, microbiologist, or polymer chemist—and drawn upon not only his or her own skills, but also taken advantage of certain specialized skills of others on the team, e.g., to solve a given problem.*

First, cosmetic formulation and pharmaceutical formulation are two different fields of science. The prior patents and publications in these two scientific areas are different between these two fields. Relating to the '802 Patent, what is common to these two arts is the ability to formulate a product.

B. The Level of Ordinary Skill

It is my opinion that Amiji's definition in Paragraph 28 is for a person of extraordinary skill in the art. As argued *supra*, the person of ordinary skill is not one who would be able to invent the '802 claimed inventions from scratch. He merely needs to make and use it. The specification of the '802 Patent presents ten formulations having similar ingredients, each of which satisfies the claim

limitations. The person of ordinary skill needs to be a person who typically prepares formulations of this type. The educational background cited by Amiji exceeds that of the person of ordinary skill. This person does not need to possess an M.S. degree in chemical engineering or pharmaceutical sciences. The inventor, Ashok Wahi, has a degree in mechanical engineering.

In my opinion, the minimum requirement for a person of ordinary skill is that he should have adequate experience in making chemical formulations. This person does not need an advanced degree. Even an undergraduate degree is unnecessary. This individual can be a chemical laboratory technician who has several years experience in making chemical formulations of the type discussed in the patent specification. At least, he must have taken undergraduate courses in organic and polymer chemistry, as well as courses in physics and biology. He must understand the concepts of static electricity as well as electrostatic attraction and repulsion. He must know what is a cationic agent and be able to identify ingredients that fit this category. He must know what is a biocidic agent and be able to identify ingredients that fit this category. He must understand the concepts of adhesion and cohesion. Finally, he must understand the various categories of harmful airborne particles, such as bacteria, viruses, pollen, and other airborne allergens. This does not require an advanced degree.

C. Knowledge of the Person of Ordinary Skill

The person of ordinary skill is familiar with all art prior to the effective filing date of the '802 Patent. He would know how to create all of the formulations in the specification of the '802 Patent. However, for the method of claim 1 of the

'802 Patent or the formulation of claim 2 of the '802 Patent to be obvious to this person of ordinary skill, based upon his level of skill and knowledge in the art of chemical or pharmaceutical formulation, he would have been required to conclude that a formulation applied to a person's nostrils would be able to inhibit inhalation of and subsequent infection from harmful particles *via* creation of an electrostatic field. He would have to understand how to manipulate adhesion and cohesion of the formulation so as to hold these harmful particles in place until they could be inactivated. Multiple prior art references at the time would have needed to teach or suggest such a method and formulation such that the person of ordinary skill would have been motivated to combine the references to make the claimed invention. The type of formulation recited in claims 1 and 2 should be so familiar to him that it would have been obvious for him to create it. However, in that case, prior to conceiving such a formulation, he could not be permitted to see the '802 Patent. The '802 Patent is not prior art.

VII. U.S. PATENT NO. 8,163,802 (THE '802 PATENT)

The '802 Patent is shown as Exhibit 1 of the Amiji Report. The '802 Patent discloses and claims a method and formulations, which applied to a person's nostrils, electrostatically captures harmful particles that the person would otherwise inhale, holds those particles in place, and renders them harmless. The process can be thought of as CATCH, HOLD, and KILL.

The patent consists of an abstract, a specification, and twenty-three claims.

A. The Abstract

The abstract discloses:

> A product to reduce and method of reducing the risk of inhalation of harmful substances by applying a formulation composition to a substrate or the skin in close proximity of one or more nostrils. This formulation, when applied creates an electrostatic field having a charge. The electrostatic field attracts airborne particulates of opposite charge to the substrate that are in close proximity to the substrate close to the skin and a biocidic agent renders microorganisms coming in contact the substrate or skin less harmful.

B. The Specification

In the Background of the Invention section of the specification, the Applicant defines the problem. Normally, a person inhales a huge amount of airborne particulate matter through his nose with every breath. Probably, most of the inhaled particles are harmless. However, inhalation of certain particles can trigger allergic reactions or can cause infection and illness. The section further describes that some people use face masks to filter out these irritants. However, these are inadequate and inefficient for their purpose. The section proceeds to

describe compositions previously patented by the same inventor[1] that create an electrostatic field around the nose that helps to filter out charged harmful particles. These compositions act merely to filter some, but not all harmful particles so as to prevent them from reaching the nose. Although this material offers some protection against particles that are inhaled passively, they cannot completely deal with particles that have their own internal means for overcoming the electrostatic forces. The particles are not captured and they are not held in place. These compositions are merely filters.

The objects of the invention listed in the specification are:

1. to provide a composition that can be readily applied to the exterior region around the nostril and/or slightly inside the edge of the nostril or near the vicinity of the source of release with method and compositions capable of capturing particulates and microorganisms;

2. to have the capability to hold it for a duration from being dislodged in to the air stream again;

3. to provide a composition that can be applied near the vicinity of the source of release or to the area around the exterior of and/or slightly inside the edge of the nostril that will inactivate, kill, or render harmless a microorganism, which has been captured and held by the composition;

4. to provide a composition that can be applied to a filter substrate for improving the substrates ability to trap and hold particulates and microorganisms and to simultaneously inactivate, kill, or render harmless the microorganisms so trapped. Such filter substrate could be placed in the close proximity of the skin near the path of inhalation, near the source of release of such particulates while the inhaler is at a distance or both; and

5. to provide a method of prophylactically preventing or of substantially reducing the risk of infection by an infectious agent without the utilization of ingested antiviral and/or antibacterial agents.

[1] The Section describes U.S. Patent 6,844,005 issued to Wahi, also the inventor listed on the '802 Patent.

Object #1 describes CATCHING. Object #2 describes HOLDING. Object #3 describes KILLING. Object #4 describes CATCHING, HOLDING, and KILLING.

The specification then lists the bacterial and viral diseases that can be caused through inhalation. It next lists the environmental particulate diseases that can be caused through inhalation. The specification lists the ingredients that make up the various formulations that meet the criteria listed in the above five objectives. Among the ingredients listed are (1) a surfactant, (2) a thickener, and (3) a binder. A surfactant is a substance that lowers the surface tension between a liquid and another material. A thickener is a substance that increases the viscosity of a liquid without affecting its other properties. A binder (or binding agent) is a material or substance that holds or draws other materials together to form a cohesive whole mechanically, chemically, by adhesion or cohesion.

Then, there are ten actual formulations listed in tables. In those listed formulations, concentrations of many of the ingredients are listed in ranges. However, all of the formulations listed in the tables will function to achieve the five objectives and will act as recited in the claims. A person of ordinary skill should have no difficulty creating the formulations listed in the tables. That person is a skilled formulator. He should be able to adjust the concentrations of the various ingredients to achieve the ideal composition that meets the criteria expressed in the five objectives *supra*.

C. <u>The Claims</u>

The claims at issue in this lawsuit are claims 1, 2, 6, and 7. The Amiji Report alleges that claims 1, 2, 6, and 7 are invalid (1) for being directed to ineligible subject matter under 35 U.S.C. § 101; (2) for lack of credible utility; (3) for lack of enablement; (4) for lack of adequate written description; (5) for being anticipated by prior art; and (6) for being obvious in view of the prior art.

1. Claim 1

1 A method for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation wherein a formulation is applied to skin or tissue of nasal passages of the individual in a thin film, said method comprising:

a) electrostatically attracting the particulate matter to the thin film;

b) holding the particulate matter in place by adjusting the adhesion of the thin film to permit said thin film to stick to the skin or tissue and by adjusting the cohesion of the formulation to provide adequate impermeability to the thin film; and,

c) inactivating the particulate matter by adding at least one ingredient that would render said particulate matter harmless.

Claim 1 is an independent claim. It is a stand-alone method claim. The preamble lists the purpose or use for the method. However, the words of the preamble are closely related to the body of the claim. The object nouns of the claim are first revealed in the preamble:

- harmful particulate matter,
- an individual,
- a formulation,
- skin or tissue (of nasal passages of the individual), and
- a thin film.

Thus, the preamble becomes an integral part of the claim because without it, the claim would be indefinite. Thus, the process uses a formulation that is applied to the skin or tissue of the nasal passages of an individual in a thin film to accomplish the process denoted by the steps recited in the body of the claim.

Essential to the claim is the formation of a thin film on the skin or tissue of the individual's nasal passages.

The method (process) claim has three steps:

a) CATCHING - *i.e.,* electrostatically attracting the particulate matter to the thin film;

b) HOLDING - *i.e.,* holding the particulate matter in place; AND

c) KILLING - *i.e.,* inactivating the particulate matter.

Step (a) requires that the formulation should contain an ingredient that creates and electrostatic field, the charge of which would attract harmful particles that have an opposite charge.

The claim further recites how steps (b) and (c) are to be accomplished.

STEP (b) - recites holding the particulate matter in place by ***adjusting the adhesion*** of the thin film to permit said thin film to stick to the skin or tissue and by ***adjusting the cohesion*** of the formulation to provide adequate impermeability to the thin film. This is performed by ***adding ingredients to the formulation***, *e.g.,* (1) a surfactant, (2) a thickener, and (3) a binder, among others. The formulation needs to adhere to the skin or tissue of the nasal passages in a thin film. The thin film also needs to be sticky and viscous so as to both adhere to the skin or tissue and to hold the particulate matter in place. Given the disclosure in the specification, a person of ordinary skill as a formulator would know which ingredients to include in the formulation to adjust the adhesive and cohesive properties of the formulation. This is done all by chemical and pharmaceutical formulators all the time. Getting the concentrations correct to

produce an ideal formulation would not consume undue experimentation given that the ingredient ranges of the example formulations are provided in the tables.

STEP (c) - recites inactivating the particulate matter by ***adding at least one ingredient*** that would render said particulate matter harmless. Biocides are among the class of ingredients that would accomplish this step. However, the ingredient concentrations are important to distinguish between preservative action and biocidic action. Once again, the concentration ranges given in the ten example formulations work as described in the specification.

2. Claim 2

2. A formulation for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation wherein the formulation is applied to skin or tissue of nasal passages of the individual in a thin film, said formulation comprising at least one cationic agent and at least one biocidic agent, and wherein said formulation, once applied:

a) electrostatically attracts the particulate matter to the thin film;

b) holds the particulate matter in place by adjusting the adhesion of the thin film to permit said thin film to stick to the skin or tissue and by adjusting the cohesion of the formulation to provide adequate impermeability to the thin film; and,

c) inactivates the particulate matter and renders said particulate matter harmless.

Claim 2 is an independent claim. It is a stand-alone formulation claim. A formulation claim is for both a composition of matter and a manufactured article. The preamble lists the use for the formulation. However, the words of the preamble are closely related to the body of the claim. The objects of the claim that are first listed in the preamble:

- a formulation,
- harmful particulate matter,
- an individual,
- skin or tissue (of nasal passages of the individual), and

- a thin film.

Thus, the preamble becomes an integral part of the claim because without it, the claim would be indefinite. Thus, the claimed formulation is applied to the skin or tissue of the nasal passages of an individual in a thin film. The formation of a thin film on the nasal passages of the individual is a mandatory aspect of the claim.

The transitional word or phrase is 'comprising,' thus providing for elements or ingredients that must be present in the formulation, but may include additional elements or ingredients. Further, there may exist additional limitations, which may be recited in dependent claims.

Although appearing in the same paragraph as the preamble, but following the transitional word, 'comprising,' are:

- at least one cationic agent, and
- at least one biocidic agent.

A cationic agent is a substance that produces a positive electrostatic charge. The ingredients of the formulation must include one cationic agent, but more of them may be present.

A biocidic agent (or biocide) is a substance that destroys or inhibits the growth or activity in living organisms. The ingredients of the formulation must include one biocidic agent, but more of them may be present.

Although the two above limitations appear in the same paragraph as the preamble, the body of the claim begins immediately following the word, 'comprising.'

Once again the formulation contains ingredients that do three things: (a) CATCH, (b) HOLD, and (c) KILL. The ingredients, when joined together, must do all three things:

(a) CATCH - *i.e.*, the formulation electrostatically attracts the particulate matter to the thin film;

(b) HOLD - *i.e.*, holds the particulate matter in place; AND

(c) KILL - inactivates the particulate matter and renders said particulate matter harmless.

The cationic agent is the ingredient in the formulation that CATCHES the harmful particulate matter by electrostatically attracting it to the thin film. (*I.e,* ELEMENT (a).) It is well known that almost all harmful airborne particles are negatively charged. These include dust particles, mites, pollen, and microbes. Thus, because the cationic agent produces a positive electrostatic charge in the thin film on the surface of the individual's nasal passages, harmful particles floating in the vicinity of the individual's nose will be attracted to the thin film. They will be CAUGHT.

ELEMENT (b) - recites that the formulation holds the particulate matter in place by ***adjusting the adhesion*** of the thin film to permit said thin film to stick to the skin or tissue and by ***adjusting the cohesion*** of the formulation to provide adequate impermeability of the thin film. This is done by ***adding ingredients to the formulation***, *e.g.*, (1) a surfactant, (2) a thickener, and (3) a binder, among others. The formulation needs to adhere to the skin or tissue of the nasal passages in a thin film. The thin film also needs to be sticky and viscous so as to both adhere to the skin or tissue and to hold the particulate matter in place.

Given the disclosure in the specification, a person of ordinary skill as a formulator would know which ingredients to include in the formulation to adjust the adhesive and cohesive properties of the formulation. This is done by chemical and pharmaceutical formulators all the time. Getting the concentrations correct to produce an ideal formulation would not consume undue experimentation given that the ingredient ranges of the example formulations are provided in the tables.

ELEMENT (c) - recites that the formulation inactivates the particulate matter, and renders it harmless. This task is performed by the ***at least one biocidic agent***. It is important to note that biocides are also used as preservatives in many products currently on the market. The purpose of a preservative is to prevent decay and to extend the lifetime of these products. The ability of the formulation of the '802 Patent to inactivate virtually all harmful particles coming in contact with the thin film depends upon the concentration of the at least one biocidic agent (to KILL) as well as the concentrations of the other ingredients (to CATCH and HOLD) the harmful particles in place.

The '802 Patent was issued on April 24, 2012. Prior to 2012, during the pendency of the patent application, Plaintiff Trutek Corp. ("Trutek"), formulated a product initially named NasalGuard® MAPB™,[2] which was formulated based upon the example formulations shown in the specification of the '802 Patent. The acronym MAPB™ was never used on any product manufactured, licensed, or sold by Trutek. All of the products sold by Trutek between 2012 and the current date are based upon the specification and claims of the '802 Patent. The technology for these subsequent products is still referred to internally by Trutek

[2] MAPB™ is an acronym for **M**ulti-**A**cting **P**article **B**locker.

as MAPB™. Trutek's products all use the term NasalGuard® as a part of their brand name.[3]

Prior to the '802 Patent being issued, Trutek submitted samples of MAPB™ gel to Max Neeman International[4] to ascertain their efficacy as a preventive treatment for the common cold and influenza. The study was conducted over 8 weeks on 600 healthy subjects, divided evenly between a group that used the MAPB™ gel and a control group. The study concluded that "MAPB nasal application gel was considered as an efficacious and safe gel in prevention of common cold and/or flu in healthy subjects." A portion of the study report is attached hereto as Exhibit D.

3. Claims 6 and 7

Claims 6 and 7 are dependent claims that depend from claim 2. Thus, claim 6 and claim 7 must be read as though they are a part of claim 2. All of the limitations of claim 2 are incorporated therein. Claim 6 states that the at least one cationic agent of the formulation of claim 2 is Benzalkonium Chloride. Claim 7 states that the at least one biocidic agent of the formulation of claim 2 is Benzalkonium Chloride. Benzalkonium Chloride is a known cationic agent and a known biocidic agent. It is used as an ingredient in the '802 Patent formulations, and functions effectively in a concentration of 0.25% to 1% by weight.

[3] The brand NasalGuard® is a registered trademark in several countries as well as in the United States.
[4] Max Neeman Medical International, Ltd. is a research institute in New Delhi, India. It was acquired by JSS Medical Research, Inc. in 2015.

VIII. REBUTTAL TO BLUEWILLOW'S ALLEGATIONS OF INVALIDITY

A. The Amiji Report did not make a clear and convincing showing that claims 1, 2, 6, and 7 are invalid for being directed to ineligible subject matter under 35 U.S.C. § 101.

Paragraph 202 on page 95 of the Amiji report states:

> *The '802 Patent is directed to the effects of a law of nature or a natural phenomena, namely the principle that like charges repel each other, while unlike charges attract, e.g., a positive charge attracts a negative charge. While the Challenged Claims of the '802 patent recite additional elements, each of those additional claim elements are either conventional steps that are well known to a POSA or depend on the very same law of nature or natural phenomena. Thus, in my opinion, the '802 Patent claims do not recite any inventive concept that would transform the law of nature into a patent eligible invention.*[1]

The author continues with an analysis in Paragraphs 203 - 211 for four pages to allege that the claims are directed to laws of nature and natural phenomena, and that this represents ineligible subject matter. He points out that electrostatic attraction is a natural phenomenon. Amiji Pg. 95, ¶ 203. He alleges that Claims 1, 2, 6, and 7 are directed to electrostatic attraction, which is a natural phenomenon. *Id.* He alleges that attracting oppositely charged particles, such as airborne contaminants is similarly a natural phenomenon. *Id.* at ¶ 204. He then states, "With respect to the second step of the § 101 test, it is also my opinion that each of the additional elements of the Challenged Claims recite nothing more than well-understood, routine and conventional activity or are directed to the very same law of nature or natural phenomena." *Id.* at ¶ 205. Further, he indicates that there is no inventive step because a person of ordinary

[1] POSA is Amiji's acronym for Person of Skill in the Art. This person is referred to in my expert report as a "Person Having Ordinary Skill In The Art," "PHOSITA," and "person of ordinary skill."

skill would know how to direct his activities toward harnessing this natural phenomenon.

Patentable subject matter under 35 U.S.C. § 101 includes new and useful inventions that claim processes, machines, manufactured articles, compositions of matter, and any new or useful improvements thereof. There are two issues relevant to § 101 – utility and subject matter eligibility. This section is devoted to subject matter eligibility. The issue of utility will be dealt with in Section VIII-B *infra*.

The first step in a § 101 analysis is to determine whether the claimed invention is one of the types of inventions patentable. Claim 1 of the '802 Patent recites a method, which is otherwise known as a process. It is a series of steps required to accomplish a task. Claims 2, 6, and 7 recite a formulation, which is both a manufactured article and a composition of matter. Thus, claims 1 and 2 recite inventions that are covered under § 101.

The second step is to determine whether the invention's claims wholly embrace non-man-made judicial exceptions to patentability, *e.g.,* laws of nature, physical phenomena, and abstract ideas, or whether "it is a particular practical application of a judicial exception." *Diamond v. Chakrabarty,* 447 U.S. 303, 309 (1980). *See also* MPEP § 2106(II). "While abstract ideas, physical phenomena, and laws of nature are not eligible for patenting, methods and products employing abstract ideas, physical phenomena, and laws of nature to perform a real-world function may well be. In evaluating whether a claim meets the requirements of 35 U.S.C. 101, the claim must be considered as a whole to

determine whether it is for a particular application of an abstract idea, physical phenomena, or law of nature, and not for the abstract idea, physical phenomenon, or law of nature itself." *Id.*, citing *Diamond v. Diehr*, 450 U.S. 175, 188 (1981).

Here, the '802 Patent does not claim electrostatic attraction or repulsion. It does not claim that positive and negative particles are attracted to each other. Nor does it claim the natural phenomena of adhesion, cohesion, or biocidic action. Instead, claim 1 recites a process that utilizes electrostatic attraction, adhesion, cohesion, and biocidic action. And, claims 2, 6, and 7 claim a manufactured article and composition of matter that utilize electrostatic attraction, adhesion, cohesion, and biocidic action.

As in claim 2, inclusion of a cationic agent ingredient in a formulation that causes negatively charged particles to be attracted to the formulation is not the equivalent of claiming electrostatic attraction itself. The claim does not wholly embrace the natural phenomenon of electrostatic attraction. It is instead a formulation that contains an ingredient that produces a positive electrostatic charge in sufficient concentration to attract negatively charged airborne particles. It is a practical invention that utilizes a natural phenomenon. By analogy, a claimed invention reciting a nuclear reactor that utilizes Einstein's law $E=mc^2$ does not wholly embrace or claim the law itself.

In Paragraphs 206 - 211 of the Amiji Report, the author states that the claims recite elements already known to persons of ordinary skill and allegations that the patent fails to adequately describe the invention.

In my opinion, Amiji misinterprets 35 U.S.C. § 101 and is generally unaware of the law and the steps that USPTO patent examiners take to examine for subject matter eligibility.

Moreover, USPTO Patent Examiner Raymond Henley III examined the application that issued as the '802 Patent. It is the first task of a USPTO patent examiner to determine subject matter eligibility under § 101. It is a threshold task performed by all patent examiners. This is codified in MPEP § 2106. Under a clear and convincing evidentiary standard, in order to prove invalidity based on ineligible subject matter, the challenger would need to show either that Examiner Henley did not seek to determine whether the claims were directed to eligible subject matter or that no reasonable examiner would have allowed the application to issue as a patent based on the conclusions put forth by Amiji.

In my opinion, the Amiji Report did not make a clear and convincing showing that claims 1, 2, 6, and 7 are invalid for being directed to ineligible subject matter under 35 U.S.C. § 101.

B. <u>The Amiji Report did not make a clear and convincing showing that claims 1, 2, 6, and 7 are invalid for lack of credible utility</u>.

In the Amiji Report, the author states the following:

> *As an object of the claimed invention, the '802 Patent states that "to accomplish the present invention, a formulation having at least one polyquaternary ammonium compound is prepared, such compounds, alone or together capable of creating an electrostatic field on and around a surface to which it is applied." '802 patent at 4:39-43.*

Pg. 99. ¶ 213.

> *A person skilled in the art reading the '802 patent specification, however, would understand that while the '802 patent does provide a laundry list of possible formulations, it does not include any data or test results for any of the formulations described, demonstrating to a person skilled in the art that there is a substantial likelihood that the claimed invention will work by "electrostatically attracting" particulate matter to a thin film applied to the nasal passages and holding the particulate matter in place through adhesion to the thin film in order to electrostatically inhibit such harmful particulate matter from infecting an individual. Nor does the '802 patent even provide any discussion or suggestion of what types of tests or procedures could be employed by a person skilled in the art to determine whether such formulations would work as described and claimed. Finally, the '802 patent also does not include any explanation or suggestion that the claimed invention is likely to work based on any similarities or analogies to other compositions or formulations that are known to work in a similar manner.*

Id. at ¶ 214.

Once again, Amiji misunderstands the law. 35 U.S.C. § 101 states that a patented invention must be useful. This is the § 101 utility requirement. There are two aspects relevant to a utility determination. The first is satisfied when a patentee asserts a practical use for his invention. Here, the preambles of claim 1 and 2 teach the practical use of "inhibiting harmful particulate matter from infecting an individual through nasal inhalation." Claims 6 and 7 incorporate the use recited in claim 2 by reference. MPEP § 2107 instructs patent examiners as follows:

> *Practical considerations require the Office to rely on the inventor's understanding of his or her invention in determining whether and in what regard an invention is believed to be "useful." Because of this, Office personnel should focus on and be receptive to assertions made by the applicant that an invention is "useful" for a particular reason.*

Thus, if the inventor asserts that his invention is useful, patent examiners are instructed to rely on that assertion. However, "[A]n application must show

that an invention is useful to the public as disclosed in its current form, not that it may prove useful at some future date after further research. Simply put, to satisfy the 'substantial' utility requirement, an asserted use must show that the claimed invention has a significant and presently available benefit to the public." *In re Fisher,* 421 F.3d 1365, 1371 (Fed. Cir. 2005).

"Rejections under 35 U.S.C. 101 based on a lack of credible utility have been sustained by federal courts when, for example, the applicant failed to disclose any utility for the invention or asserted a utility that could only be true if it violated a scientific principle, such as the second law of thermodynamics, or a law of nature, or was wholly inconsistent with contemporary knowledge in the art." *In re Gazave,* 379 F.2d 973, 978 (C.C.P.A. 1967). Who would say that, "inhibiting harmful particulate matter from infecting an individual through nasal inhalation" violates any law of nature or defies contemporary knowledge.

The Amiji Report's allegation of lack of credible utility spans from Paragraph 212 on page 99 until Paragraph 217 on page 101. Paragraphs 215-217 deal mainly with novelty and enablement. They discuss that uses of cationic agents, Benzalkonium Chloride, quaternary ammonium compounds, are well known by persons of ordinary skill. Claims 1, 2, 6, and 7 describe a use that is beneficial to the public, and the specification and claims provide information that a person of ordinary skill would employ to make and use the formulations described therein without undue experimentation.

Both subject matter eligibility and utility are inquiries that need to be made regarding 35 U.S.C. § 101. Inquiries into novelty are best made relative to

statutes 35 U.S.C. §§ 102 and 103. The inquiry into utility of the claims of the '802 Patent is a threshold issue that a patent examiner must perform. This is codified in MPEP § 2107. Under a clear and convincing evidentiary standard in order to prove invalidity based lack of credible utility, the challenger would need to show either that Examiner Henley did not seek to determine whether the claims had credible utility or that no reasonable examiner would have allowed the application to issue as a patent based on the conclusions put forth by Amiji.

In my opinion, the Amiji Report did not make a clear and convincing showing that claims 1, 2, 6, and 7 are invalid for lack of credible utility under 35 U.S.C. § 101.

C. The Amiji Report did not make a clear and convincing showing that claims 1, 2, 6, and 7 are invalid for lack of enablement.

Utility and enablement are two separate but related properties of a claim. The enablement requirement stems from 35 U.S.C. § 112(a):

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.

Enablement means that practice of the invention must not require undue experimentation, although reasonable experimentation by a person having ordinary skill in the art is permitted. *White Consol. Indus., Inc. v. Vega Servo-Control, Inc.,* 713 F.2d 788 (Fed. Cir. 1985). The enablement requirement is met if the description enables any mode of making and using the claimed invention. *Engel Indus., Inc. v. Lockformer Co.,* 946 F.2d 1528 (Fed. Cir. 1991).

For a claim to be enabled, it must relate to matters taught in the specification. The specification of a patent often teaches several ways that the inventor conceived to implement the invention. Each way to implement the invention is called an embodiment. It is sometimes referred to as an example. The inventor is only required to describe a single embodiment. In that case, the single embodiment must be what the inventor conceives at the time as being the best mode of operation. However, when multiple embodiments are disclosed, only one of them is the best mode, and the inventor is not required to disclose which embodiment is the best mode.

In the '802 Patent, ten different embodiments are taught in the specification. Each one is a formulation that has been shown to work. They all read on the claims of the '802 Patent, and particularly on claims 1, 2, 6, and 7. In the Amiji report, the author complains that the formulations do not have specific percentage concentrations, but appear in ranges. He alleges that this would prevent one from reproducing the various formulations. However, it is known that the embodiments listed in the written description do not need to describe a manufacturing specification. The description does not need to teach a person of ordinary skill something with which he is already familiar. Though the formulations' ingredients are listed by concentration ranges, all of the listed concentrations will create formulations that are fit for their intended purposes. A formulator, who is a person of ordinary skill, would be able to make each of the formulations without undue experimentation. The NasalGuard® product formulations that use the MAPB™ technology derive from the ten embodiments

described in the specification. The use of the formulations in preventing infections from harmful microbial particles (*e.g.,* viruses) is described in the specification. That the product is efficacious against the common cold and influenza is demonstrated by the clinical study of Exhibit D. A person of ordinary skill could easily use the claimed formulation for its intended purpose once he has fabricated it.

In the Amiji Report, respectively, the author complains that claims 1 and 2 are broad. Independent claims are supposed to be broad. An inventor is entitled to as much of his invention that is not taught by the prior art.

The '802 Patent issued after allowance of U.S. Patent Application Serial No. 12/467,271. In a first office action on the merits of the '271 Application on August 25, 2011, Examiner Raymond Henley III issued a non-final rejection of claims 1-23 under 35 U.S.C. § 112, First Paragraph (now § 112(a)) based on lack of enablement. The 08/25/2011 office action is attached hereto as Exhibit E.

The enablement problem seen by Examiner Henley had to do with the term "preventing," as used in independent claims 1, 2, and 8. Claims 1 and 2, as originally submitted with the filing of the '271 Application are shown in Exhibit F attached hereto. The term "preventing" appears in the first lines of both claims 1 and 2. In the Office Action, the Examiner stated:

> *Here, the objective truth of the statement that an infection, which is taken to mean the introduction of an infections element through the outside of a given host and into the system of such host. ... may be prevented, ... i.e., a material is ever kept from introduction into the system of a host, is doubted because the present claims merely recite a pharmaceutical composition while an effective prevention against the introduction of all infectious material into a host, especially where such material does not cause any pathology,*

> *would require that the exterior system of the host be completely blocked so as to preclude any infections material passing through such system and arriving within the system of the host.*
>
> *In reading the specification as a whole, it appears the tenor thereof is that infections, whether they cause a pathology or not, may be* ***inhibited*** [2] *rather than be prevented. The former allowing at least one infectious material to pass into the system of the host rather than the latter which indicates that not even one of the infectious material is allowed to infect, i.e., pass into the system of the host.*

The Examiner explained how to overcome the rejection:

> *In order to overcome the rejection set forth infra, it is suggested that Applicant consider amending claims 1, 2, and 8 so as to delete the term "preventing" and replacing it with the term "inhibiting." While the latter is not specifically set forth in the present specification, it is nevertheless deemed that the concept thereof clearly finds support therein when the specification's teachings are taken as a whole, i.e., no new matter would be introduced by the introduction of the term "inhibition" in the claims.*

As a result of this non-final rejection, the Applicant amended claims 1, 2, and 8 by following the suggestion of the examiner and substituting "inhibiting' for "preventing" on the first line of each of the three independent claims. That was the only change made to the claims. Amended claims 1 and 2 are identical to claims 1 and 2 of the '802 Patent. On March 12, 2012, without further comment, Examiner Henley issued a Notice of Allowance for claims 1-23 of the '271 Application.

During prosecution, Examiner Henley explored the issue of enablement under 35 U.S.C. § 112(a). Other than requiring a minor amendment, the fact finder determined that the disclosure in the specification enabled the claims. At the time, Raymond Henley III was a senior examiner.

[2] Emphasis supplied.

Under the clear and convincing evidentiary standard, the challenger would need to show that no reasonable examiner would have rejected the claims for lack of enablement, and to provide clear and convincing evidence that Examiner Henley was incorrect in his decision to allow the claims.

In my opinion, the Amiji Report did not make a clear and convincing showing that claims 1, 2, 6, and 7 are invalid for lack of enablement.

D. <u>The Amiji Report did not make a clear and convincing showing that claims 1, 2, 6, and 7 are invalid for lack of adequate written description</u>.

The Amiji Report states as follows:

> *It is my opinion that the '802 patent specification does not reasonably convey to a person skilled in the art that the inventor was in possession of any formulation or composition that would operate in the manner claimed in the '802 patent as of the filing date of the application.*
>
> *Amiji,* Pg. 108, ¶ 236.
>
> *While the '802 patent specification describes numerous formulations and different ranges of components that are purportedly within the scope of the claimed invention, the specification provides no data or testing of any kind demonstrating to a person of skilled in the art that the mere fact of applying a thin film having a positive charge will operate to "electrostatically attract" negatively charged particulate matter, adhering such particulate matter to the thin film, thereby inhibiting the particulate matter from infecting an individual. Nor does the '802 patent specification provide any indication to a person skilled in the art that the inventor even tested any of the formulations disclosed in the patent to assess whether they actually operate to electrostatically inhibit harmful particulate matter from infecting an individual through nasal inhalation. In other words, a person skilled in the art reading the '802 patent would understand that the inventor merely had a wish or hope that the claimed invention would operate in the manner described.*
>
> *Amiji,* Pg. 109, ¶ 237.

It is astounding that by saying, "the specification provides no data or testing of any kind demonstrating to a person of skilled in the art that the mere fact of applying a thin film having a positive charge will operate to “electrostatically attract” negatively charged particulate matter, adhering such particulate matter to the thin film, thereby inhibiting the particulate matter from infecting an individual." Amiji fails to recognize basic laws of physics relating to static electricity. Any person who took a course in high school physics in the United States knows that oppositely charged particles attract each other, and similarly charged particles repel each other. A patent specification needs no experimental data to demonstrate this.

There are ten actual formulations listed in tables. In those listed formulations, concentrations of many of the ingredients are listed in ranges. Specific concentrations are not required because all of the formulations listed in the tables will function as recited in the claims. A person of ordinary skill should have no difficulty creating the formulations listed in the tables. That person is a skilled formulator. Amiji complains that the written description provides no data to show that the particulate matter adheres to the thin film. However, among the ingredients listed are (1) a surfactant, (2) a thickener, and (3) a binder. A surfactant is a substance that lowers the surface tension between a liquid and another material. A thickener is a substance that increases the viscosity of a liquid without affecting its other properties. A binder (or binding agent) is a material or substance that holds or draws other materials together to form a cohesive whole mechanically, chemically, by adhesion or cohesion. Thickeners,

binders, and surfactants are well known to persons of ordinary skill. The specific ingredients used are listed in the ten formulations of the specification. In addition, various biocides are listed as ingredients in the ten formulations. A person of ordinary skill would know that biocides in the concentration ranges provided would adequately perform the task of inhibiting the harmful particles from infecting the individual.

A patent specification is not a scientific paper. The written description requirement of 35 U.S.C. § 112(a) is that it must be complete enough as to enable a person of ordinary skill to make and use the invention. It does not need to teach the prior art to those who are unfamiliar with it. It is not necessary to publish results of experiments. The study in Exhibit D proves that the formulations inhibit infection from cold and flu viruses as claimed. The ten formulations work. Thus, as long as a person of ordinary skill **can formulate** the example formulations, **and** as long as he **can use** any of those formulations as prescribed, the written description requirement of § 112(a) is met.

In the office action of Exhibit E, Examiner Henley stated:

> [i]*t is suggested that Applicant consider amending claims 1, 2 and 8 so as to delete the term "preventing" and replacing it with the term "inhibiting". While the latter is not specifically set forth in the present specification,* ***it is nevertheless deemed that the concept thereof clearly finds support therein when the specification's teachings are taken as a whole*** [3]

Thus, the fact finder clearly considered whether the written description requirement of § 112(a) was fulfilled. He evaluated the listed formulations, and stated that the claims find "support when the specification's teachings are taken

[3] Emphasis added.

as a whole." Thus, under a clear and convincing standard, invalidity of the claims for failure to fulfill the written description requirement can be made only if it can be shown that no reasonable examiner would have allowed the claims.

In my opinion, the Amiji Report did not make a clear and convincing showing that claims 1, 2, 6, and 7 are invalid for lack of adequate written description.

E. The Amiji Report did not make a clear and convincing showing that claims 1, 2, 6, and 7 are invalid in view of Wahi '488 alone, or in combination with Rolf.

Wahi '488 refers to U.S. Patent No. 5,468,488 issued to Ashok Wahi on November 21, 1995. A copy of Wahi '488 is attached to the Amiji Report as his Exhibit 5.

1. Validity Analysis Based On Wahi '488 Alone.

Wahi '488 teaches and claims a method for restricting the flow of airborne contaminants into a nasal passage. It involves creating an electrostatic field in an area near a human nasal passage. The electrostatic field may either repel or attract airborne contaminants or both." *Id.* Abstract.

Wahi '488 is closely related to U.S. Patent No. 5,674,481 ("Wahi '481" – attached to the Amiji Report as Exhibit 6) issued to Ashok Wahi on October 7, 1997. The Wahi '481 patent is a continuation patent of and claims priority to Wahi '488. The teachings of the two patents are virtually identical. While Wahi '488 teaches and claims a method, Wahi '481 teaches and claims products that implement the method.

For a claim of an issued patent to become invalid based upon prior art, the prior art must teach or suggest each and every element of that claim. When such a condition arises from reference to a single prior art reference, invalidity is based upon anticipation under 35 U.S.C. § 102(a). "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California,* 814 F.2d 628, 631 (Fed. Cir. 1987).

As discussed in Section VII of my report *supra*, independent claim 1 of the '802 Patent recites a method for electrostatically inhibiting harmful particles from infecting an individual by applying a formulation to the individual's nasal passages in a thin film. The three elements (a, b, and c, respectively) of the claim recite CATCHING (electrostatically attracting), HOLDING (holding), and KILLING (inactivating the particulate matter and rendering it harmless).

Independent claim 2 of the '802 Patent recites a formulation product for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation, wherein the formulation is applied to the skin or tissue of the individual's nasal passages in a thin film. The formulation contains, among other ingredients, at least one cationic agent and at least one biocidic agent. The three elements (a, b, and c, respectively) recite that the formulation product CATCHES (electrostatically attracts), HOLDS, and KILLS (inactivates the particulate matter and renders it harmless).

Dependent claims 6 and 7 merely recite a limitation on the claim 2 formulation that the cationic agent and biocidic agent are Benzalkonium Chloride.

The recitation of CATCH, HOLD, and KILL are essential elements all four claims. In order to anticipate these claims, the prior art must teach all of the elements of CATCH, HOLD, and KILL. Further, the claims must teach application of the formulation in a thin film. HOLDING must be accomplished by adjusting the adhesion and cohesion of the formulation. And, relating to claim 2, the formulation must contain at least one cationic agent and at least one biocidic agent.

The objective of the '488 method and the '481 product is merely to restrict the flow of airborne contaminants into an individual's nose by inhalation. The '481 Patent teaches that creation of an electrostatic field near an individual's nasal passages can inhibit (or lessen) the number of airborne contaminants that are inhaled by the individual. Nowhere in either the '488 or '481 Patents is it taught that a product is applied to the skin or tissue of the nasal passages. If the electrostatic field is negatively charged, then negatively charged particles will be repelled by the field, and they will be deflected from the nostrils and not inhaled. On the other hand, it the electrostatic field is positively charged, then negatively charged particles will be attracted to the formulation, *i.e.,* they will be caught and will not be inhaled. Neither the '488 nor the '481 Patent teaches HOLDING or KILLING. Nothing in the patents teaches that the particles will not be dislodged and inhaled after being CAUGHT. Moreover, nothing in the patents teaches that the particles are KILLED (inactivated and rendered harmless). Therefore, Wahi '488 cannot anticipate claim 1, and Wahi '481 cannot anticipate claims 2, 6, or 7.

An allegation of invalidity of claims 1, 2, 6, and 7 under 35 U.S.C. 102(a) cannot stand.

In addition, Examiner Henley considered both Wahi '488 and Wahi '481 during examination of the application that issued as the '802 Patent. Exhibit C (attached hereto) shows the examiner's initials next to items 14 (Wahi '488) and 15 (Wahi '481). Because a clear and convincing showing is required to invalidate a patent, the fact that the examiner considered these two prior art references and allowed the patent application to issue as the '802 Patent should be given great deference.

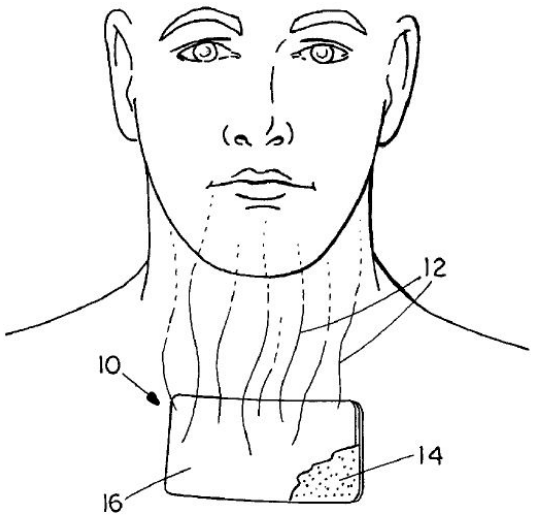
In my opinion, the Amiji Report did not make a clear and convincing showing that claims 1, 2, 6, and 7 are invalid in view of Wahi '488 alone.

2. Validity Analysis Based On Wahi '488 In Combination With Rolf.

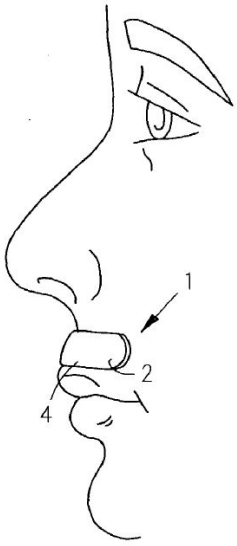
As argued *supra*, for a claim of an issued patent to become invalid based upon prior art, the prior art must teach or suggest each and every element of that claim. 35 U.S.C. § 103 provides that even if a claim is not anticipated under §102, it may still be unpatentable if the differences between the claimed invention and the prior art as a whole would have been obvious before the effective filing date of the claimed invention to a person of ordinary skill. When evaluating a claim for patentability, an examiner may combine two or more prior art references to determine whether the claimed invention would have been obvious to a person of ordinary skill at the time the invention was conceived. *Pre-AIA* 35 U.S.C. § 103(a).

In the Amiji Report, the author alleged that claims 1, 2, 6, and 7 would have been unpatentable over the combination of Wahi '488 with U.S. Patent Application Publication 2004/0071757 A1 (hereinafter, "Rolf") published by the USPTO on April 15, 2004 of U.S. Patent Application No. 10/458,078 submitted by David Rolf. The Rolf Application Publication is attached to the Amiji Report as Exhibit 4.

The Rolf application never issued as a patent. Attached hereto as Exhibit G is USPTO office actions generated during prosecution of Rolf's patent application. In that office action, the examiner rejected all of Rolf's pending claims based on obviousness double patenting, and under statutes 35 U.S.C. §§ 112, 102, and 103. The first of these rejections was based upon a non-statutory, judicially created doctrine often referred to as obviousness double patenting. The claims of Rolf were deemed obvious over the teachings of an earlier patent listing him as an inventor, *viz.,* U.S. Patent No. 6,090,403 ("Block") issued on July 18, 2000. A copy of Block is attached hereto as Exhibit H.



The invention made by Block (shown in the above drawing) is a patch (10) impregnated with a vaporizable decongestant (12), wherein the patch adheres to the skin below the individual's face *via* an adhesive. This invention is similar in action to Vicks® VapoRub® ointment, a well known product that is applied to a person's chest. In both products, vaporizable decongestants evaporate and are inhaled by the individual. "Once vaporized, the aromatic decongestant is available for natural inhalation through the nose or mouth to help relieve one or more of the symptoms of cough, colds, nasal or chest congestion and related symptoms." *Block* Abstract. Vicks® VapoRub® ointment and the Block patch function the same way.



The invention of the Rolf Application (shown in the figure above) is strikingly similar, except that the patch (1) is placed closer to the person's nose. Another difference is that Rolf's patch is impregnated with "essential oils." Rolf defines essential oils as "highly odoriferous, liquid components obtained from plant tissue. Essential oils are usually captured by Steam distillation, a process

whose origins can be traced back to ancient Mesopotamia. Unlike ordinary vegetable oils, such as corn and olive, plant essences are highly volatile and will evaporate if left in the open air." Rolf Abstract. Essential oils (15) typically include a mixture of one or more terpenes, esters, aldehydes, ketones, alcohols, phenols, and/or oxides. These functional classes of compounds are responsible for the therapeutic properties and distinct fragrance of the essential oil. *Id*. at [0064]. From Paragraph [0063] to [0073], Rolf lists a myriad of substances that he dubs essential oils. Paragraph [0147] provides a list of preservatives that can be used in his invention. Among them is Benzalkonium Chloride. However, this ingredient is used only as a preservative, which Rolf defines a preservative as any substance which prevents bacterial growth, mold growth, fermentation, and/or decomposition. Paragraphs [0151] - [0152] list many anti-viral agents that may be included on the adhesive patch. Among them is lysine hydrochloride. Rolf proceeds to list 87 embodiments, which are also recited in 87 claims. He also presents 16 example formulations.

Of the 87 claims, three are independent. Claim 86 is a kit claim not relevant to the current validity analysis. Claim 1 reads:

> 1. A method for preventing a respiratory infection in a mammal at risk thereof, the method comprises contacting a live respiratory pathogen at risk of entering the respiratory tract of the mammal with a therapeutically effective amount of an essential oil, such that the live respiratory pathogen is inactivated upon contact with the essential oil, wherein the source of the essential oil is a patch located in the vicinity of the nasal passageway of the mammal.

Claim 80 reads:

> 80. A method for preventing a respiratory viral infection in a mammal at risk thereof, the method comprises contacting a live respiratory virus with a prophylactically effective amount of an essential oil such that the live respiratory virus is inactivated upon contact with the essential oil, wherein the source of the essential oil is a patch located in the vicinity of the nasal passageway of the mammal.

These two independent claims represent the essence of Rolf's teachings.

There is no doubt that Rolf is able to function similarly as Block. Were the active agent to be a vaporizable decongestant such as menthol, Rolf would exhibit improvement over Block because the activated adhesive patch is closer to the individual's nose.

However, the laws of physics do not enable Rolf's invention. Assuming a randomized distribution of harmful or infectious particles in the vicinity of Rolf's patch, some particles will graze by the patch. For argument's sake, assume that Rolf's patch is impregnated with a biocide, those particles that contact the biocide for a sufficient time period may be deactivated. The deactivated particles will then dislodge from the patch, and they will float along with all the other airborne particles. Some will be inhaled, and some will not. In any event, most of the inhaled particles will not be deactivated. Rolf does not CATCH or HOLD the particles, and the KILL function is random and insignificant.

Reviewing Pages 4-6 of the USPTO office action shown in Exhibit G for Rolf's patent application, the examiner provided detailed reasoning explaining why his claims were not enabled. The examiner had serious doubts whether Rolf's invention would work as disclosed in writing.

If Rolf is not enabled for the purpose intended in claims 1 and 80, it is not possible to combine Rolf with Wahi '488 to reproduce method claim 1 or formulation claims 2, 6, and 7.

Moreover, under 35 U.S.C. § 103 a combining prior art references must be read to encompass all of the limitations of the claim under evaluation. Claims 1 and 2 of the '802 Patent encompass the elements of CATCH, HOLD, and KILL, The teachings of Wahi '488 enable the CATCH element. Rolf does not address the HOLD function, and his KILL function is not enabled. Therefore, when combining the teachings of Wahi '488 with those of Rolf, essential elements of Claims 1, 2, 6, and 7 are not present.

Therefore, it is my opinion that the Amiji Report did not make a clear and convincing showing that claims 1, 2, 6, and 7 are invalid in view of Wahi '488 alone, or in combination with Rolf.

F. The Amiji Report did not make a clear and convincing showing that claims 1, 2, 6, and 7 are invalid in view of Wadstrom alone, or in combination with Rolf.

Wadstrom refers to U.S. Patent Application Publication No. 2006/0163149 A1 (hereinafter, "Wadstrom") published by the USPTO on July 27, 2006 of U.S. Patent Application No. 10/559,464 submitted by Torkel Wadstrom, *et.al*. Wadstrom is attached to the Amiji Report as Exhibit 3.

1. Validity Analysis Based On Wadstrom Alone.

Wadstrom discloses his invention in a plurality of "aspects." That aspect most relevant to this analysis is the tenth aspect. However this aspect does not

stand alone. It is directly or indirectly dependent upon the first, second, and third aspects.

> [*A*]*ccording to a first aspect, a product for absorption purposes consisting of an in water insoluble support matrix wherein the support matrix is substituted with a hydrophobic entity which in turn is connected to a positively charged entity (other than said in water insoluble support matrix.*

Wadstrom at [0006]

> *According to a second aspect a method for the manufacture of a product according to the first aspect is provided, wherein a hydrophobic entity connected to a positively charged entity, is attached to a support matrix, preferably using an elimination reaction involving a good leaving group on the hydrophobic entity and a high pH.*

Id.

> *According to a third aspect of the present invention there is also provided a product obtainable by a method according to the second aspect.*

Id.

> *According to a tenth aspect of the present invention there is also provided a nasal spray comprising a product according to the first aspect or third aspect for capturing microorganisms, preferably airborne and/or liquid borne microorganisms, as well as viruses, preferably airborne and/or liquid borne viruses in the nasal cavity.*

Id.

> *The support matrix may further be present in particulate form allowing the application of the product for absorption purposes according to the first or third aspect of the present invention by means of a nasal spray or an ointment.*

Wadstrom at [0007]

The tenth aspect is also recited in claim 64, which depends from Claim 50.

Claim 50: A product for absorption purposes consisting of an in water insoluble support matrix wherein the support matrix is substituted with a hydrophobic entity which in turn is connected to a positively charged entity, other than said in water insoluble support matrix.

Claim 64: A nasal spray comprising a product according to claim 50.

I agree with the author's overview of Wadstrom set forth in Paragraphs 82, 83, and 84 on Pages 33 and 34 of the Amiji Report. Wadstrom's first, second, and third aspect teaches a positively charged formulation connected to a water resistant support matrix. That support matrix may take the form of a cellulose fiber, a face mask, a laboratory filter, a tea bag, *etc.* "The support matrix may further be present in particulate form allowing the application of the product for absorption purposes according to the first or third aspect of the present invention by means of a nasal spray or an ointment." *Wadstrom* at [0006].

Admittedly, the positively charged formulation will attract and CATCH negatively charged particles, and when used in a nasal spray, the formulation in combination with the particulate support matrix will perform that function. However, in Paragraph 109 on Page 45 of the Amiji Report, the author states, "Wadstrom discloses that its claimed formula “efficiently bound” at least two different types of bacteria. (Ex. 3 at [0031].)" However, at [0031], the disclosed support matrix consisted of non-treated and treated (QUAB 342) cellulose fiber filters." The disclosure is silent as to any bonding that occurs when a nasal spray is introduced into an individual's nostrils.

Independent claims 1 and 2 of the '802 Patent recite as follows:

1 A method for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation wherein a formulation is applied to skin or tissue of nasal passages of the individual in a thin film, said method comprising:

a) electrostatically attracting the particulate matter to the thin film;

b) holding the particulate matter in place by adjusting the adhesion of the thin film to permit said thin film to stick to the skin or tissue and by adjusting the cohesion of the formulation to provide adequate impermeability to the thin film; and,

c) inactivating the particulate matter by adding at least one ingredient that would render said particulate matter harmless.

2. A formulation for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation wherein the formulation is applied to skin or tissue of nasal passages of the individual in a thin film, said formulation comprising at least one cationic agent and at least one biocidic agent, and wherein said formulation, once applied:

a) electrostatically attracts the particulate matter to the thin film;

b) holds the particulate matter in place by adjusting the adhesion of the thin film to permit said thin film to stick to the skin or tissue and by adjusting the cohesion of the formulation to provide adequate impermeability to the thin film; and,

c) inactivates the particulate matter and renders said particulate matter harmless.

As was argued in Section VII *supra* (regarding the '802 Patent), the steps of claim 1 are of a formulation CATCHING, HOLDING, and KILLING harmful particulate matter. The functions of the formulation of claim 2 is to CATCH, HOLD, and KILL the harmful particulate matter.

Also, as discussed earlier, when considering a single prior reference to show claim invalidity, we are talking about anticipation under 35 U.S.C. § 102(a). As such, that single prior art reference must teach every element in the

challenged claim. Claim invalidity may only be established using clear and convincing evidence.

Here, Wadstrom merely teaches CATCHING the contaminants. It is silent regarding HOLDING and KILLING. Because claims 1 and 2 require all three elements to be present, those claims of the '802 Patent cannot be anticipated by Wadstrom alone. Regarding dependent claims 6 and 7, if claim 2 is patentably valid, then claims 6 and 7 must also be valid because they incorporate all of the limitations of claim 2 therein.

Therefore, it is my opinion that the Amiji Report did not make a clear and convincing showing that claims 1, 2, 6, and 7 are invalid in view of Wadstrom alone.

2. **Validity Analysis Based On Wadstrom In Combination With Rolf.**

As discussed *supra*, while Wadstrom teaches the CATCH function for harmful particles, it is silent regarding the HOLD and KILL functions. In addition, as argued *supra*, Rolf is not enabled for either CATCH, HOLD, or KILL. Thus, Rolf cannot be combined with Wadstrom to encompass all of the elements of claims 1, 2, 6, and 7 as is required by 35 U.S.C. § 103.

Even if they could be combined, Rolf does not teach HOLDING, and its teachings of KILLING are dubious. The combination of Rolf with Wadstrom does not encompass all of the elements of the challenged claims of the '802 Patent.

Therefore, it is my opinion that the Amiji Report did not make a clear and convincing showing that claims 1, 2, 6, and 7 are invalid in view of Wadstrom alone, or in combination with Rolf.

G. <u>The Amiji Report did not make a clear and convincing showing that claims 1, 2, 6, and 7 are invalid in view of Baker '189 alone or Baker '476 alone, or in combination with Rolf, or Khaled, or Rabe, or Katz, or Wahi '790</u>.

This statement at Section XI on Page 74 of the Amiji Report is indefinite and ambiguous. It is very difficult to interpret the statement as it does not take any standard form that the USPTO employs for rejection of claims due to anticipation under 35 U.S.C. § 102(a) or due to obviousness under 35 U.S.C. § 103. I reason that Amiji might mean that both Baker '189 alone and Baker '476 separately anticipate claims 1, 2, 6, and 7 of the '802 Patent under 35 U.S.C. § 102(a). However, the statement of combinations of the other prior art in the alternative is unintelligible. I do not understand precisely what Amiji is saying.

- "Baker '189" refers to U.S. Patent No. 6,559,189 issued to James R. Baker, Jr., *et.al.,* on May 6, 2003, which is attached to the Amiji Report as Exhibit 8.
- "Baker '476" refers to U.S. Patent Application Publication No. 2009/0143476 A1, published by the USPTO on June 4, 2009 for U.S. Patent Application No. 11/928,427 by James R. Baker, Jr., *et.al.*, which is attached to the Amiji Report as Exhibit 9.
- "Khaled" refers to U.S. Patent Application Publication No. 2007/0243237 A1, published by the USPTO on October 18, 2007 for U.S. Patent Application No. 11/404,025 by Mazen Khaled, *et.al.*, which is attached to the Amiji Report as Exhibit 7.
- "Rabe" refers to U.S. Patent No. 6,531,142 issued to Thomas Elliot Rabe, *et.al.* on March 11, 2003, which is attached to the Amiji Report as Exhibit 12.
- "Katz" refers to U.S. Patent Application Publication No. 2002/0006961 A1, published by the USPTO on January 17, 2002 for U.S. Patent Application No. 09/846,722 by Stanley E. Katz, *et.al.*, which is attached to the Amiji Report as Exhibit 13.
- "Wahi '790" refers to U.S. Patent Application No. 2003/0161790 A1, published by the USPTO on August 28, 2003 for U.S. Patent Application No. 10/082,978 by Ashok Wahi, *et.al.*, which is attached to the Amiji Report as Exhibit 14.

  Note that the Wahi '790 patent application issued as U.S. Patent No. 6,844,005 ("Wahi '005"), which is attached to my report as Exhibit I.

1. Validity Analysis Based On Baker '189 Alone.

Baker '189 teaches an antimicrobial composition contained within an oil-water nanoemulsion adjuvant. Among the disclosed embodiments are those where the composition is administered nasally. The nanoemulsion adjuvant is able to form a thin film. The function of the composition is to prevent or treat infection or disease resulting from various microbes. Among the disclosed ingredients are at least one cationic agent and at least one biocide. In at least one embodiment, the composition contains benzalkonium chloride as an ingredient.

However, Baker '189 is silent regarding electrostatic attraction. But, it may be inferred that the presence of a cationic agent in sufficient concentration in some nasally administered embodiment will attract the microorganisms electrostatically. Notwithstanding, Baker '189 is also silent regarding holding the microorganisms in place, and there is no mention of adjusting the adhesion and cohesion of the nanoemulsion to achieve adequate impermeability. This element cannot be inferred from Baker '189 alone.

As argued *supra*, for there to be anticipation under 35 U.S.C. § 102(a), there must be a single reference that teaches all of the elements in the challenged claims. If the reference is silent regarding a single element in the claim, then anticipation is not achieved.

Baker '189 teaches the CATCH and KILL elements. However, it is silent regarding the HOLD element. Holding the harmful particles in place is a critical element in claims 1 and 2. Thus, neither claim 1 nor claim 2 of the '802 Patent is

anticipated by Baker '189. Further, if claim 2 is not anticipated, then claims 6 and 7 cannot be anticipated because dependent claims 6 and 7 incorporate by reference all of the limitations of claim 2.

Thus, it is my opinion that the Amiji Report did not make a clear and convincing showing that claims 1, 2, 6, and 7 are invalid in view of Baker '189 alone.

1. Validity Analysis Based On Baker '476 Alone.

In Paragraph 101 on Page 42, the Amiji Report states, "Baker '476 filed on October 30, 2007, is a continuation-in-part of the '189 patent and has the same disclosure of the '189 patent in addition to disclosing an embodiment comprising CPC and a benzyl ammonium chloride compound (specifically, alkyldimethyl 1-3,4-dichlorobenzyl ammonium chloride). (Ex. 8, at [0232].)"

Like its parent application, Baker '476 also teaches an antimicrobial composition contained within an oil-water nanoemulsion adjuvant. Among the disclosed embodiments are those where the composition is administered nasally. The nanoemulsion adjuvant is able to form a thin film. The function of the composition is to prevent or treat infection or disease resulting from various microbes. Among the disclosed ingredients are at least one cationic agent and at least one biocide. In at least one embodiment, the composition contains benzalkonium chloride as an ingredient.

However, as with its parent application, Baker '476 is silent regarding electrostatic attraction. But, it may be inferred that the presence of a cationic agent in sufficient concentration in some nasally administered embodiment will

attract the microorganisms electrostatically. Notwithstanding, Baker '476 is also silent regarding holding the microorganisms in place, and there is no mention of adjusting the adhesion and cohesion of the nanoemulsion to achieve adequate impermeability. This element cannot be inferred from Baker '476 alone.

As argued *supra*, for there to be anticipation under 35 U.S.C. § 102(a), there must be a single reference that teaches all of the elements in the challenged claims. If the reference is silent regarding a single element in the claim, then anticipation is not achieved.

Baker '476 teaches the CATCH and KILL elements. However, like its parent application, it is silent regarding the HOLD element. Holding the harmful particles in place is a critical element in claims 1 and 2. Thus, neither claim 1 nor claim 2 of the '802 Patent is anticipated by Baker '476. Further, if claim 2 is not anticipated, then claims 6 and 7 cannot be anticipated because dependent claims 6 and 7 incorporate by reference all of the limitations of claim 2.

Thus, it is my opinion that the Amiji Report did not make a clear and convincing showing that claims 1, 2, 6, and 7 are invalid in view of Baker '476 alone.

3. <u>Combinations with Rolf</u>

As argued *supra*, under 35 U.S.C. § 103, prior art references may be combined if a person of ordinary skill would do so to produce the claimed invention at the effective filing date. Hindsight is impermissible. The '802 Patent may not be used as a template to show obviousness over itself. The references themselves must teach and suggest the combination. However, when combining

the references, the combination must encompass all elements of the challenged claim. The combination may not be silent about any element.

As discussed *supra,* claims 1, 2, 6, and 7 recite the elements of CATCH, HOLD, and KILL. Further, while both Baker '189 and Baker '476 teach CATCH and KILL, neither reference teaches HOLD.

As argued previously, Rolf is not enabled (*see* Exhibit G) for what it attempts to claim. Rolf unsuccessfully attempted to teach and recite the KILL element. Thus, it cannot be combined with either Baker '189 or '476. Yet, notwithstanding lack of enablement, Rolf is silent regarding the HOLD element. Therefore, combining Rolf with either Baker '189 or '476 would not encompass all elements of claims 1, 2, 6, and 7 of the '802 Patent.

Therefore, it is my opinion that the Amiji Report did not make a clear and convincing showing that claims 1, 2, 6, and 7 are invalid in view of Baker '189 or Baker '476 in combination with Rolf.

4. Combinations with Khaled

Khaled teaches the combination of cationic and anionic polyelectrolytes into a layered thin film that coats and bonds to various substrates (*e.g.,* metal, wood, rubber, plastic, *etc.*). "The positively charged polyelectrolytes and the negatively charged polyelectrolytes arrange themselves into a polyelectrolyte complex, rather than an alternating multi-layer structure, due to the electrostatic attraction between particles, allowing for the formation of a thin film with optimal coverage of the substrate." *Khaled* at Abstract. "The polymeric components form a polyelectrolyte complex, which is a true molecular blend of the individual

polymeric components." *Id.* at [0041]. Khaled's thin film layer is antimicrobial with biocides dispersed within the thin film or dissolved therein. Paragraph [0053] lists a large number of representative biocides. Khaled relates that, "the multilayer containing the antibiotic was placed in a solution containing staphylococcus aureus bacteria. Subsequent investigation of the solution indicated a decrease in growth of the bacteria population compared to a solution containing an uncoated surface." *Id.* at [0052].

Atoms become positively charged cations when they lose electrons. Atoms become negatively charged anions when they absorb electrons. Cationic agents are positively charged, and anionic agents are negatively charged. When interspersed, electrons from the anionic polyelectrolytes migrate to the cationic polyelectrolytes, tending to make the Khaled's thin film electrostatically neutral.

Nowhere does Khaled express or imply that microorganisms are electrostatically attracted to the thin film (*i.e.,* the CATCH function). Further, Khaled is silent as to whether microorganisms are held in place by the thin film (*i.e.*, the HOLD function). However, Khaled says that his antimicrobial film inhibits the growth of a bacteria population (*i.e.,* the KILL function).

Claims 1, 2, 6, and 7 of the '802 Patent encompasses CATCHING, HOLDING, and KILLING. Baker '189 and '476 encompass CATCHING and KILLING, but are silent regarding HOLDING. Because Khaled does not teach HOLDING, the combination of Khaled with Baker '189 or with Baker '476 will not produce a method or formulation that is encompassed by all of the elements of the claims of the '802 Patent that are at issue.

Therefore, it is my opinion that the Amiji Report did not make a clear and convincing showing that claims 1, 2, 6, and 7 are invalid in view of Baker '189 or Baker '476 in combination with Khaled.

5. Combinations with Rabe

At Page 43 in Paragraph 103 of the Amiji Report, in his overview of the Rabe patent, the author states:

> *Rabe discloses "stabilized electrostatically-sprayable topical compositions" comprising a liquid insulating material (e.g., volatile silicones, volatile hydrocarbons), one or more conductive materials (e.g., C8-C20 isoparaffin, water, alcohols, glycols, polyols and ketones, etc.), a particulate materials and thickeners (e.g., wax or clays). (Ex. 12, at Abstract; 4:12-5:13; 5:14-55; 7:21-30.)*

Further, in Paragraph 104 on the same page, the author states:

> *Sprays can include quatemium/benzalkonium compounds (e.g., Quaternium-18/Benzalkonium Bentonite. (Id., at 8:20-44), Various further anti-microbial agents can also be included. (Id. at 9:11-13.)*

I agree with Amiji's overview of the Rabe patent. Rabe teaches compositions that are used for treating a person's skin and are intended to be applied thereto. Although Rabe's compositions are electrostatically-sprayable, prior to application they do not exhibit electrostatic properties. In the preferred embodiments, the compositions are sprayed onto an individual's skin using a sprayer that imparts a charge to the droplets by applying an electric voltage at the spray nozzle assembly. *Rabe* at 13:53-14:2. The electrostatic charge of the droplets may be either positive or negative (depending on how the voltage is applied), but droplets having a positive charge is preferred. *Id.* at 14:2.

> *How the spray works is generally explained, for example, by explaining that the product is a fine mist of product droplets that are charged so that they stay separated during application and are uniquely attracted to the face versus non-target areas such as the hair, clothing, etc., yet needs no blending. Id.* at 16:59.

Thus, the composition taught by Rabe has no relation to anything taught or claimed in the '802 Patent other than imparting an electrostatic charge to the skin. Further, Rabe teaches alternate application methods.

> *The topical compositions can alternatively be applied to the skin to form the discontinuous films by silk screen techniques or the like, and additionally by using application techniques which provide product deposition via the use of normal forces (i.e., forces perpendicular to the skin surface). Id.* at 18:7.

In addition:

> *In one embodiment, the fluid topical skin product is absorbed into the porous material and then "blotted" onto the skin using forces perpendicular to the skin (as opposed to tangential, or shearing forces). This application technique uses the pore size and pore spacing of the material to create the discontinuous deposition patter. Id.* at 18:55.

Nowhere in Rabe is there any mention of application of an anti-bacterial or an antimicrobial formulation or application to the nasal passages. In cases where Rabe's composition exhibits an electrostatic charge on the skin there may be some electrostatic attraction. However, electrons from the air often deposit on the skin thus causing skin irritation. When there are enough electrons, hairs on the skin will stand erect. A person's skin is normally negatively charged. Imparting a material having a positive electrostatic charge to the skin adsorbs the electrons and neutralizes the skin's natural negative charge. There will be no electrostatic attraction of negatively charged airborne contaminants. Rabe does not exhibit the functions of CATCHING, HOLDING, or KILLING.

As argued *supra*, to show that the combination of Rabe with Baker '189 or Baker '476 makes the '802 Patent's claims 1, 2, 6, or 7 obvious to a person of ordinary skill, the combined references would need to encompass all of the claimed elements, *i.e.*, CATCH, HOLD, and KILL. While Baker '189 and Baker '476 teach CATCH and KILL, they are silent regarding HOLD. Their combination with Rabe does not remedy the situation.

Therefore, it is my opinion that the Amiji Report did not make a clear and convincing showing that claims 1, 2, 6, and 7 are invalid in view of Baker '189 or Baker '476 in combination with Rabe.

6. Combinations with Katz

At Page 43 in Paragraph 105 of the Amiji Report, the author states:

> *Katz discloses multiple nasal sprays including BAC. (See Ex. 13, at [0078]-[0081]). For example, paragraph [0079] provides that "1.5 fl. oz. (45 ml) of Afrin® moisturizing saline mist solution may be purchased commercially over the counter (Schering-Plough, Memphis, Tenn.). The solution contains water, PEG-32, sodium chloride, PVP, disodium phosphate, sodium phosphate, benzalkonium chloride, and disodium EDTA." (Ex 13, at [0079].)*

While Katz uses benzalkonium chloride as a preservative, it is very dilute (*i.e.,* 1:5000). *Katz* at [0081]. While Katz discloses that his formulations exhibit an antimicrobial effect (KILL), there is no indication that the concentration of benzalkonium chloride is sufficient to exhibit any electrostatic attraction (CATCH). He is silent regarding holding harmful particles in place (HOLD). Katz is silent regarding the CATCH and HOLD functions.

As argued *supra*, to show that the combination of Katz with Baker '189 or Baker '476 makes the '802 Patent's claims 1, 2, 6, or 7 obvious to a person of

ordinary skill, the combined references would need to encompass all of the claimed elements, *i.e.*, CATCH, HOLD, and KILL. While Baker '189 and Baker '476 teach CATCH and KILL, they are silent regarding HOLD. Their combination with Katz does not remedy the situation.

Therefore, it is my opinion that the Amiji Report did not make a clear and convincing showing that claims 1, 2, 6, and 7 are invalid in view of Baker '189 or Baker '476 in combination with Katz.

7. Combinations with Wahi '790

The Amiji Report listed 33 references that he purported to be prior art that he considered in forming his opinions. *Amiji Report* Pages 8-12. The author listed Wahi '790 as Exhibit 14. He stated, "I understand that none of these references were before the Patent Office during prosecution of the '802 Patent except "Wahi '488" and "Wahi '481." *Id.* at Pg. 12, ¶ 25. However, Wahi '790 is the USPTO publication of U.S. Patent Application No. 10/082,978 by Ashok Wahi, *et.al*. The Wahi '790 patent application issued as U.S. Patent No. 6,844,005 ("Wahi '005"), which is attached to my report as Exhibit I. Wahi '005 was disclosed to the USPTO upon filing of the patent application in an Information Disclosure Statement, and it was considered by Examiner Henley during examination. (*See* Exhibit C, attached hereto.) The first paragraph in Wahi '790 is titled, "INCORPORATIONS BY REFERENCE," while the first paragraph in Wahi '005 is titled, "REFERENCE TO RELATED CASES." Otherwise, the specifications of the two references are identical. The application received a notice of allowance at the first office action on the merits. No

amendments were made to the claims. Therefore, by having considered Wahi '005 during patent prosecution, since Wahi '790 is a virtually identical document, Examiner Henley considered the teachings of Wahi '790 when he allowed the '802 Patent to issue.

Wahi '005 (as well as Wahi '790) was an improvement over Wahi '481 that was made six years later. The primary difference between the two patents lie with the cationic agents used in the latter patent, which provide the source for a stronger electrostatic field. Wahi '005 utilizes poly (dimethyl diallyl ammonium chloride) polymer included in the product in an amount of at least 10% by weight.

The objective of the Wahi '481 and Wahi '005 (*i.e.* '790) products are merely to restrict the flow of airborne contaminants into an individual's nose by inhalation. Both the '005 Patent and the '481 Patent teach that creation of an electrostatic field near an individual's nasal passages can inhibit (or lessen) the number of airborne contaminants that are inhaled by the individual. Nowhere in either the '005 or '481 Patents is it taught that a product is applied to the skin or tissue of the nasal passages. Instead an electrostatic field is created in the vicinity of the person's nose. If the electrostatic field is positively charged, then negatively charged particles will be attracted to the formulation, *i.e.,* they will be caught and will not be inhaled (*i.e.,* the CATCH function). Neither the '005 nor the '481 Patent teaches HOLDING or KILLING. Nothing in the patents teaches that the particles will not be dislodged and inhaled after being CAUGHT. Moreover, nothing in the patents teaches that the particles are KILLED (inactivated and rendered harmless).

Baker '189 and Baker '476 are silent regarding the HOLD function. For any combination with Baker '189 or Baker '476 to successfully present a case for obviousness, the second reference must teach the HOLD function. However, Wahi '790 does not teach the HOLD function. Therefore, the combination of Wahi '790 or Wahi '005 with Baker '189 or Baker '476 cannot render claims 1, 2, 6, or 7 of the '802 Patent obvious.

In addition, Examiner Henley considered Wahi '005 during examination of the application that issued as the '802 Patent. Exhibit C (attached hereto) shows the examiner's initials next to item 16 (Wahi '005). Because a clear and convincing showing is required to invalidate a patent, the fact that the examiner considered this prior art reference and allowed the patent application to issue as the '802 Patent should be given great deference.

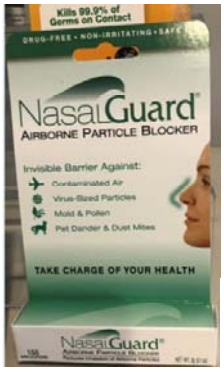
IX. Secondary Consideration - Commercial Success

As stated by the Federal Circuit:

> *evidence of secondary considerations may often be the best probative and cogent evidence in the record. It may often establish that an invention appearing to have been obvious in light of the prior art was not. It is to be considered as part of all the evidence, not just when the decisionmaker remains in doubt after reviewing the art.*
> *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538-40 (Fed. Cir. 1983).

> *Thus when differences that may appear technologically minor nonetheless have a practical impact, particularly in a crowded field, the decision-maker must consider the obviousness of the new structure in this light. Such objective indicia as commercial success, or filling an existing need, illuminate the technological and commercial environment of the inventor, and aid in understanding the state of the art at the time the invention was made.*
> *Continental Can Co. USA v. Monsanto Co.*, 948 F.2d 1264 (Fed. Cir. 1991).

The '802 Patent issued in 2012. On or around that time, Trutek formulated over-the-counter products that were based on the '802 Patent. The products had different brand names and packaging, and they were marketed and sold in the United States and abroad. All products sold in the United States had the '802 Patent number printed on the packaging. The following photographs show some of these products.



The court in *Stratoflex*, 715 F.2d at 1539, has unequivocally stated that for commercial success of a product embodying a claimed invention to have true relevance to the issue of nonobviousness, that success must be shown to have in some way been due to the nature of the claimed invention, as opposed to other economic and commercial factors unrelated to the technical quality of the patented subject matter. Thus, a "nexus is required between the merits of the claimed invention and the evidence offered. If that evidence is to be given substantial weight enroute to [a] conclusion on the obviousness issue."

Since 2012, approximately seven million tubes of the '802 patented products have been sold worldwide. On Amazon.com, a typical price for the NasalGuard Airborne Particle Blocker® is $14.85. Thus, the sales have been substantial. At this point, it is difficult to determine which are initial sales or repeat sales. Clearly, seven million people did not purchase the products. A substantial number must have been repeat sales. The large number of repeat sales indicates satisfaction with the products. Satisfaction is necessarily based on the ability of the product to inhibit harmful particles from infecting the purchaser through nasal inhalation. Harmful particles would be, *e.g.*, pollen, dust, allergens, cold and flu viruses, *etc.* Trutek has done minimal advertising. In my opinion, commercial success of the NasalGuard® products is due to the products' performance according to the '802 Patent.

X. CONCLUSIONS

After reading and understanding the Amiji Report and references to the exhibits thereto, I conclude that the author failed to show by a clear and convincing standard of proof that claims 1, 2, 6, or 7 of the '802 Patent are invalid either under 35 U.S.C. §§ 101, 112, 102(a), or 103. The examiner determined that the subject matter and utility of the claims at issue conform to the requirements of 35 U.S.C. § 101. The examiner also determined that the written description conformed to the requirements of 35 U.S.C. § 112(a). The examiner further determined that the patented claims were enabled. None of the prior art references cited by the Amiji Report as invalidating the claims at issue fail to overcome the presumption of validity according to a clear and convincing standard of proof. Furthermore, when attempting to define a person having ordinary skill in the art, the author actually defined a person having extraordinary skill. That designation is critical because a person of extraordinary skill would make predictions based on prior art, which a person of ordinary skill would not make.

Date: ___August 12, 2022___

Respectfully submitted,

Amirali Y. Haidri, Esq.

IN THE UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF MICHIGAN

SOUTHERN DIVISION

TRUTEK CORP.,
Plaintiff,

v.

BlueWillow Biologics, Inc.
ROBIN ROE 1 through 10, gender neutral fictitious names, and ABC CORPORATION 1 through 10 (fictitious names).

Defendants.

CIVIL ACTION No. 2:21-cv-10312-SJM-RSW

CERTIFICATE OF SERVICE

Undersigned hereby states that on August 15, 2022, the attorneys for Plaintiff caused the foregoing document to be served upon all counsel of record, via electronic service.

Stanley H. Kremen
Attorney at Law
4 Lenape Lane
East Brunswick, NJ 08816
Telephone: (732) 593-7294
shk@shk-dplc.com
Attorney for the Plaintiff

Keith Altman
The Law Office of Keith Altman
38228 West 12 Mile Road, Suite 375
Farmington Hills, Michigan 48334
Telephone: (248) 987-8929
keithaltman@kaltmanlaw.com
Attorney for the Plaintiff

EXHIBIT A

AMIRALI Y. HAIDRI
110 HILLSIDE AVENUE, SUITE 104
SPRINGFIELD, NEW JERSEY 07081-3007
(908) 688-8700
E-MAIL AMIRALI Y HAIDRI@AOL.COM

BAR ADMISSIONS: NEW YORK (1981), NEW JERSEY(1983) AND
U.S. PATENT AND TRADEMARK OFFICE (REG. NO. 29,164)
U.S. DISTRICT COURTS FOR THE DISTRICT OF NEW JERSEY AND THE SOUTHERN DISTRICT OF NEW YORK
CERTIFIED AS A CIVIL TRIAL ATTORNEY BY THE SUPREME COURT OF NEW JERSEY

MARTINDALE-HUBBELL RATING: BV (DISTINGUISHED)

LISTED IN: MARQUIS WHO'S WHO IN AMERICAN LAW

EDUCATION:

NEW YORK UNIVERSITY
M.S. 1983
ORGANIC CHEMISTRY

NEW YORK LAW SCHOOL
J.D. 1980
CUM LAUDE
CLASS RANK: UPPER 15%
D. GEORGE LEVINE MEMORIAL AWARD FOR THE HIGHEST GRADE IN THE LAW OF REAL PROPERTY

UNIVERSITY OF LEEDS, ENGLAND
B.S. (HONS.) CHEMICAL ENGINEERING 1971

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*RECIPIENT OF RECOGNITION AWARDS FROM THE N.J. STATE BAR ASSOCIATION

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"HOT TIPS FOR HOT LITIGATORS" NJSBA ANNUAL MEETING AND CONVENTION, MAY 18, 2011, MAY 16, 2012, AND MAY 14, 2014, ATLANTIC CITY

"IMPORTANT THINGS TO KNOW ABOUT CASES WITH INTERNATIONAL IMPLICATIONS" NJSBA MID-YEAR MEETING AND CONVENTION, NOVEMBER 8, 2011, DUBLIN, IRELAND

"LAWYER ADVERTISING, SOLICITATION OF CLIENTS AND THE USE OF SOCIAL MEDIA" HUNTERDON COUNTY BAR ASSOCIATION, NOVEMBER 22, 2011, CLINTON

"WORKERS COMPENSATION BENCH-BAR CONFERENCE" NJSBA ANNUAL MEETING AND CONVENTION, MAY 18, 2012 ATLANTIC CITY

"HOT TOPICS IN PROFESSIONAL RESPONSIBILITY" NJSBA ANNUAL MEETING AND CONVENTION, MAY 15, 2013, ATLANTIC CITY

"THE EXTRATERRITORIALITY OF UNITED STATES PATENT AND TRADEMARK LEGISLATION" NJSBA MID-YEAR MEETING AND CONVENTION, NOVEMBER 7, 2014, PARIS, FRANCE

"INTERNATIONAL LAW AND INTELLECTUAL PROPERTY: SERVICE OF PROCESS AND DISCOVERY CONSIDERATIONS UNDER THE HAGUE CONVENTION AND TRANSNATIONAL ENFORCEMENT OF JUDGMENTS" NJICLE, DECEMBER 4, 2014, NEW BRUNSWICK, NEW JERSEY

"ETHICAL RELATIONSHIPS: HANDLING CONFLICTS IN CLIENT AND ATTORNEY RELATIONS" NJSBA ANNUAL MEETING AND CONVENTION, MAY 19, 2016, ATLANTIC CITY

"RECENT DEVELOPMENTS IN PROFESSIONAL RESPONSIBILITY AND ETHICS" NJSBA ANNUAL MEETING AND CONVENTION, MAY 18, 2017, ATLANTIC CITY

"AROUND THE SKY-THE LATEST IN AVIATION, *A WEBINAR*, NJ-ICLE, MAY 26, 2022, BROADCAST BY ZOOM

MODERATOR: "STATUTE OF LIMITATIONS CONCERNS IN CRIMINAL CASES"- *A WEBINAR*, NJ-ICLE, JANUARY 24, 2013, BROADCAST FROM NEW BRUNSWICK

BAR RELATED ACTIVITIES: MEMBER: MEMBER, LATER CHAIR, PANEL 6, SUPREME COURT COMMITTEE ON FEE ARBITRATION, DISTRICT XII (2001-2006)

MEMBER: SUPREME COURT COMMITTEE ON ATTORNEY ADVERTISING (FORMER VICE CHAIR 2018/2019)

MEMBER: SUPREME COURT ADVISORY COMMITTEE ON PROFESSIONAL ETHICS

TRUSTEE: NEW JERSEY STATE BAR ASSOCIATION (2007 TO 2013)

TRUSTEE: UNION COUNTY BAR ASSOCIATION (2002 TO 2013)

NEW JERSEY STATE BAR ASSOCIATION TRUSTEE LIAISON AT VARIOUS TIMES TO: CIVIL TRIAL BAR SECTION, HEALTH AND HOSPITAL LAW SECTION, INSURANCE LAW SECTION, INTELLECTUAL PROPERTY LAW SPECIAL COMMITTEE AND WOMEN IN THE PROFESSION SECTION (2007 TO 2013)

MEMBER (PAST AND PRESENT): NEW JERSEY STATE BAR ASSOCIATION, AMICUS STANDING COMMITTEE, DIVERSITY STANDING COMMITTEE, PROFESSIONAL RESPONSIBILITY STANDING COMMITTEE, APPELLATE PRACTICE SPECIAL COMMITTEE, AVIATION LAW SPECIAL COMMITTEE, INTELLECTUAL PROPERTY LAW SPECIAL COMMITTEE

MASTER: RICHARD J. HUGHES AMERICAN INN OF COURT

MASTER: JOHN C. LIFLAND AMERICAN INN OF COURT

MASTER: WILLIAM C. KONNER AMERICAN INN OF COURT

N.J. RULE 1:40 MEDIATOR

ARBITRATOR, MANDATORY NON-BINDING AUTOMOBILE AND PERSONAL INJURY ARBITRATION PROGRAMS OF THE MORRIS AND UNION COUNTY VICINAGES OF THE SUPERIOR COURT OF NEW JERSEY

ALUMNI RELATED ACTIVITIES:

SECOND VICE PRESIDENT, BRITISH SCHOOLS AND UNIVERSITIES CLUB OF NEW YORK (2005-2006), HONORARY SECRETARY (2011-2012)

EXPERIENCE:

(1988 TO PRESENT) SOLO PRACTITIONER; (1984 TO 1988) PARTNER, HAIDRI, GLAZER & KAMEL, PRIVATE PRACTICE CONCENTRATED IN PERSONAL INJURY, AND WORKERS' COMPENSATION PREDOMINANTLY FOR PLAINTIFFS AND PETITIONERS; HANDLED PERSONAL INJURY PROTECTION AND MEDICAL PROVIDERS' COLLECTION ACTIONS AND ARBITRATIONS; ACTED AS ARBITRATOR IN UNINSURED/UNDERINSURED MOTORIST CASES; HANDLED APPELLATE MATTERS.

DECEMBER 1982 TO JUNE 1984

LEVER BROTHERS COMPANY
EDGEWATER, NEW JERSEY
PATENT ATTORNEY

REVIEWED AND EVALUATED PATENT DISCLOSURES. PREPARED AND FILED PATENT APPLICATIONS. ASSUMED RESPONSIBILITIES FOR THE PROSECUTION OF U.S. AND FOREIGN PATENT APPLICATIONS. PREPARED CONSULTING, SECRECY AND LICENSE

AGREEMENTS, AS WELL AS INFRINGEMENT AND VALIDITY OPINIONS.

MAY 1981 TO DECEMBER 1982

TEXACO DEVELOPMENT CORPORATION
WHITE PLAINS, NEW YORK
PATENT ATTORNEY

REVIEWED DISCLOSURES FROM INVENTORS FOR PATENTABILITY, EVALUATED SEARCHES AND DRAFTED PATENT APPLICATIONS, PROSECUTED U.S. AND FOREIGN CASES INCLUSIVE OF PREPARATION AND FILING OF AMENDMENTS, APPEALS, CONTINUATIONS AND FOREIGN OPPOSITIONS.

1972 TO 1981

HASELTINE AND LAKE
NEW YORK, NEW YORK
ASSOCIATE AND DIRECTOR OF TRADEMARK DEPARTMENT

PREPARED AND FILED TRADEMARK APPLICATIONS, OPPOSITIONS, CANCELLATIONS, LICENSING OF TECHNOLOGY AND RECORDING OF LICENSES, INFRINGEMENT, PASSING OFF AND UNFAIR COMPETITION ACTIONS.

1971 TO 1972

W.P. THOMPSON & CO.
LIVERPOOL, ENGLAND
ASSOCIATE

PRINCIPALLY SAME EXPERIENCE AS HASELTINE AND LAKE WITH EMPHASIS ON BRITISH PRACTICE, REGISTERED USER RECORDATIONS AND INCIDENTAL PATENT AND DESIGN MATTERS.

EXHIBIT B

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (03-09)
Approved for use through 04/30/2009. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Not for submission under 37 CFR 1.99)

Application Number	
Filing Date	2009-05-16
First Named Inventor	Ashok Wahi
Art Unit	
Examiner Name	
Attorney Docket Number	51900-TRUTEK-009

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	1071015		1913-08-26	Adler, J.	
	2	2237954		1941-04-08	Wilson, W.R.	
	3	2433565		1947-12-30	Korman, A.	
	4	2777442		1957-01-15	Zelano, J.	
	5	3145711		1964-08-25	Beber, A.	
	6	3513839		1970-05-26	Vacante, M.	
	7	4030491		1977-06-21	Mattila, A.	
	8	4052983		1977-10-11	Bovender, C.R.	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Not for submission under 37 CFR 1.99)

Application Number	
Filing Date	2009-05-16
First Named Inventor	Ashok Wahi
Art Unit	
Examiner Name	
Attorney Docket Number	51900-TRUTEK-009

	9	4267831		1981-05-19	Aguilar, M.	
	10	4401117		1983-08-30	Gershuny, H.	
	11	4789504		1988-12-06	Ohmori, et.al.	
	12	4874659		1989-10-17	Ando, et.al.	
	13	2751906		1953-10-26	Irvine, M.E.	
	14	5468488		1995-11-21	Wahi, A.L.	
	15	5674481		1997-10-07	Wahi, A.L.	
	16	6844005	B2	2005-01-18	Wahi, A.L.	

If you wish to add additional U.S. Patent citation information please click the Add button. Add

U.S.PATENT APPLICATION PUBLICATIONS Remove

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20030223934	A1	2003-12-04	Wahi, A.L.	

If you wish to add additional U.S. Published Application citation information please click the Add button. Add

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	
Filing Date	2009-05-16
First Named Inventor	Ashok Wahi
Art Unit	
Examiner Name	
Attorney Docket Number	51900-TRUTEK-009

FOREIGN PATENT DOCUMENTS Remove

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1							☐

If you wish to add additional Foreign Patent Document citation information please click the Add button Add

NON-PATENT LITERATURE DOCUMENTS Remove

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1		☐

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

EXHIBIT C

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (03-09)
Approved for use through 04/30/2009. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Not for submission under 37 CFR 1.99)

Application Number	
Filing Date	2009-05-16
First Named Inventor	Ashok Wahi
Art Unit	1629
Examiner Name	Raymond J Henley III
Attorney Docket Number	51900-TRUTEK-009

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
/R.H./	1	1071015		1913-08-26	Adler, J.	
	2	2237954		1941-04-08	Wilson, W.R.	
	3	2433565		1947-12-30	Korman, A.	
	4	2777442		1957-01-15	Zelano, J.	
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	6	3513839		1970-05-26	Vacante, M.	
	7	4030491		1977-06-21	Mattila, A.	
/R.H./	8	4052983		1977-10-11	Bovender, C.R.	

/Raymond J. Henley III/ 08/19/2011

INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Not for submission under 37 CFR 1.99)

Application Number	
Filing Date	2009-05-16
First Named Inventor	Ashok Wahi
Art Unit	1629
Examiner Name	Raymond J Henley III
Attorney Docket Number	51900-TRUTEK-009

/R.H./	9	4267831		1981-05-19	Aguilar, M.	
	10	4401117		1983-08-30	Gershuny, H.	
	11	4789504		1988-12-06	Ohmori, et.al.	
	12	4874659		1989-10-17	Ando, et.al.	
	13	2751906		1953-10-26	Irvine, M.E.	
	14	5468488		1995-11-21	Wahi, A.L.	
	15	5674481		1997-10-07	Wahi, A.L.	
/R.H./	16	6844005	B2	2005-01-18	Wahi, A.L.	

If you wish to add additional U.S. Patent citation information please click the Add button. Add

U.S.PATENT APPLICATION PUBLICATIONS Remove

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
/R.H./	1	20030223934	A1	2003-12-04	Wahi, A.L.	

If you wish to add additional U.S. Published Application citation information please click the Add button. Add

/Raymond J. Henley III/ 08/19/2011

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	
Filing Date	2009-05-16
First Named Inventor	Ashok Wahi
Art Unit	1629
Examiner Name	R.J.Henley III
Attorney Docket Number	51900-TRUTEK-009

FOREIGN PATENT DOCUMENTS Remove

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2]	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1							☐

If you wish to add additional Foreign Patent Document citation information please click the Add button Add

NON-PATENT LITERATURE DOCUMENTS Remove

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1		☐

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature	/Raymond J. Henley III/	Date Considered	08/19/2011

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

EXHIBIT D

MAXNEEMAN
CONTRACT RESEARCH
Improving... life

A Multi-Center Study to Determine
The Safety and Efficacy of
Trutek's "Multi Acting Nasal Particle Blocker (MAPB)"
as a Preventive Treatment for Cold and Flu

Clinical Study Report

07 March 2012

CLINICAL STUDY REPORT

STUDY ID:	TTK-MAPB-MN01
SPONSOR:	Trutek Corp. 281 East Main Street Somerville, NJ 08876 United States of America Tel.: +1 908 685 1111
INVESTIGATIONAL DEVICE:	Multi Acting Nasal Particle Blocker
Study Initiation Date (First Subject Enrolled):	02 August 2011
Study Completion Date (Last Subject Completed):	12 November 2011
Name & Contact Details of Sponsor's Signatory:	Vir Narula Chief Operating Officer Trutek Corp. 281 East Main Street Somerville, NJ 08876 United States of America Tel.: +1 908 685 1111
Report Date:	7 March 2012

Confidentiality Statement

2 SYNOPSIS

Name of Company: Trutek Corp.		*(For National Authority Use only)*
Name of Product: Multi Acting Nasal Particle Blocker (MAPB) gel		
Title of the Study:	A Randomized, Prospective, Open label, Parallel group, Comparative, Multi-Center Study to Determine the Safety and Efficacy of Trutek's device "Multi Acting Nasal Particle Blocker (MAPB)" as a Preventive Treatment for Cold and/or Flu.	
Investigators:	The list of Investigators is presented in Appendix 3.	
Investigation Sites:	Three sites, one in Gurgaon and two in Jaipur, in India were selected for this study.	
Study Period:	Date of first subject enrolled: 02 August 2011 Date of last subject completed: 12 November 2011	
Objectives:	The primary objective of the study was: • To evaluate the efficacy of MAPB nasal application gel in the prevention of the common cold and/or flu The secondary objective was: • To evaluate the safety of MAPB nasal application gel in the prevention of the common cold and/or flu	
Methodology:	Randomized, prospective, open label, parallel group, comparative, multi-center study with two groups Group A: Active treatment with MAPB gel Group B: No treatment control group	
Total Number of Subjects:	Planned: 600 healthy subjects (300 subjects each in Group A and Group B)	Randomized: 600 healthy subjects (300 subjects each in Group A and Group B)
Evaluated:	Efficacy: 600 healthy subjects (300 subjects each in Group A and Group B)	Safety: 600 healthy subjects (300 subjects each in Group A and Group B)
Diagnosis and Criteria for Inclusion:	Subjects who fulfilled the following criteria were considered for enrollment into the study: 1. Male or female from 18 years to 70 years of age. 2. Willing to sign written informed consent form. 3. Willingness to comply with the test procedure.	
Investigational Device:	Multi Acting Nasal Particle Blocker manufactured by Trutek Corp. is a patent pending topical gel that filters airborne particles from entering the nasal passages.	
Duration of Administration:	MAPB gel was recommended to be applied 4 to 6 times per day for 8 weeks as directed in the package insert.	
Duration of Treatment:	The study period was for approximately 8 weeks (57 days) with a total of 2 visits, on Day 0 and Day 57, to the investigation site and 3 intermediate phone calls with the Investigator.	

Name of Company: Trutek Corp. **Name of Product:** Multi Acting Nasal Particle Blocker (MAPB) gel	*(For National Authority Use only)*
Reference Therapy:	Control group (Group B) was given no treatment.
Primary Endpoint:	The primary study endpoint was: • Percentage of subjects that were cold and/or flu free in the treatment group at the end of study as compared to the subjects who were cold and/or flu free in the no treatment group
Secondary Endpoints:	The secondary study endpoints were: • Incidence of treatment related adverse events
Statistical Methods:	**Sample Size Calculation** The sample size calculation was based on the detection of difference between two proportions. Assuming the cold and/or flu free subject rates in no treatment group (Group B) and MAPB treatment group (Group A) as 85% and 94%, respectively, detecting a difference of 9% with 95% confidence (two sided 5% level of significance) and with 90% power would require 264 subjects approximately in each group. Adjusting for anticipated 11% dropout rate and balanced randomization, a total of 594 subjects in 1:1 ratio were to be enrolled in the study. The chi-square test for proportions with continuity correction was used for these calculations. The descriptive statistics for continuous variables was presented with number (n) of non-missing observations, mean, standard deviation, median, minimum, and maximum. For categorical data, descriptive statistics was presented with number of exposed subjects, and number (n) with percentage of observations in the various categories of the endpoint, where percentage was based on the exposed subjects. Statistical significance was declared if the two-sided probability value was ≤ 0.05. For efficacy analysis, logistic regression model with treatment group as independent factor was used to compare the subjects at the end of the study. The variables, which can have influence on the cold and/or flu, were taken into consideration by using these factors in logistic regression analysis. P-values, odds ratios and corresponding 95% confidence intervals were reported. Additionally, chi-square test/Fisher exact test (small expected frequency) was used to compare the 'treatment' and the 'no treatment' groups at 5% level of significance.
Summary of Efficacy Results:	• Statistically significant higher number of subjects with cold and/or flu free status was observed in Group A than Group B at the end of the study on Day 57 • The probability of cold and/or flu was approximately 3 times higher in Group B than Group A
Summary of Safety Results:	• No Serious Adverse Device Effects (SADEs) or Serious Adverse Events (SAEs) were observed or reported in the study • Two subjects reported Adverse Device Effects (ADEs) where one reported mild sneezing and another reported vomiting. As per sole discretion of the Investigator, these Adverse Events (AEs) were

	considered to have probable and possible relationships to treatment, respectively • In both the cases there was no recurrence of the event. Hence, the subjects continued to apply MAPB gel and went on to complete the study unhindered for total study duration of 8 weeks
Conclusions:	Six hundred healthy subjects were enrolled in this prospective, open label, parallel group, comparative, multi-center study and were randomized 1:1 to either MAPB or no treatment group. The objective of the study was to evaluate the efficacy and safety of MAPB gel in prevention of cold and/or flu. Three hundred subjects randomized to Group A were instructed to apply MAPB gel 4 to 6 times a day for a period of 8 weeks and the remaining 300 subjects randomized to Group B were not given any treatment and served as the control group. At the end of study (8 weeks), 295/300 (98.3%) subjects using MAPB gel were cold and/or flu free; whereas 285/300 (95%) subjects not on any treatment were cold and/or flu-free. This difference was of statistical as well as of clinical significance. Subjects of Group B had 3 times higher probability of getting cold and/or flu than subjects of Group A. In terms of safety, none of the subjects reported any SAEs or SADEs. Two subjects in Group A reported ADE where one had sneezing and another subject had vomiting. Both the ADEs were of mild intensity. As per sole discretion of the Investigator, these ADEs were considered to have probable and possible relationships to treatment, respectively. There was no recurrence of the event in both the subjects. Hence, both of them continued to apply MAPB gel and went on to complete the study unhindered for total study duration of 8 weeks. In conclusion, MAPB nasal application gel was considered as an efficacious and safe gel in prevention of common cold and/or flu in healthy subjects.

MNI Signatures	07 MAR 2012	Bhattacharya. 7 March 2012	S. Anwar 7/March/12
	Shekar Sunkoju, Biostatistician, Max Neeman International	**Priyanka Bhattacharya** Medical Writer, Max Neeman International	**Dr. Shariq Anwar** Director, Operations Max Neeman International
Date of Report:	07 March 2012		

EXHIBIT E

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/467,271	05/16/2009	Ashok Wahi	51900-TRUTEK-009	7676

34325 7590 08/25/2011

STANLEY H. KREMEN
4 LENAPE LANE
EAST BRUNSWICK, NJ 08816

EXAMINER	
HENLEY III, RAYMOND J	

ART UNIT	PAPER NUMBER
1629	

NOTIFICATION DATE	DELIVERY MODE
08/25/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

uspto@patentsgroup.com

Office Action Summary	Application No.	Applicant(s)	
	12/467,271	WAHI, ASHOK	
	Examiner	Art Unit	
	RAYMOND HENLEY III	1629	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *5/16/2009 and papers subsequent thereto*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *1-23* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1-23* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/16/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

CLAIMS 1-23 ARE PRESENTED FOR EXAMINATION

Applicant's Information Disclosure Statement filed May 16, 2009 has been received and entered into the application. As reflected by the attached, completed copies of form PTO/SB/08, (3 sheets), the cited references have been considered.

Overcoming the Rejection Below

In order to overcome the rejection set forth *infra*, it is suggested that Applicant consider amending claims 1, 2 and 8 so as to delete the term "preventing" and replacing it with the term "inhibiting". While the latter is not specifically set forth in the present specification, it is nevertheless deemed that the concept thereof clearly finds support therein when the specification's teachings are taken as a whole, i.e., no new matter would be introduced by the introduction of the term "inhibition" in the claims.

Claim Rejection - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-23 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for, at the most, inhibition of infections, does not reasonably provide enablement for the prevention of the same, (see claims 1, 2 and 8; and thus the claims dependent therefrom). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Burden on the Examiner for Making a Rejection Under 35 U.S.C. § 112 First Paragraph

As set forth in *In re Marzocchi*, 169 USPQ 367, 370 (CCPA 1971):

"[A] [s]pecification disclosure which contains teaching of manner and process of making and using the invention in terms corresponding to the scope to those used in describing and defining subject matter sought to be patented must be taken as in compliance with enabling requirement of first paragraph of 35 U.S.C. 112 *unless there is reason to doubt the objective truth of statements contain therein which must be relied on for enabling support*; assuming that sufficient reason for such doubt exists, a rejection for failure to teach how to make and/or use will be proper on that basis, such a rejection can be overcome by suitable proofs indicating that teaching contained in specification is truly enabling." (emphasis added).

Here, the objective truth of the statement that an infection, which is taken to mean the introduction of an infectious element through the outside of a given host and into the system of such host, (see MPEP § 2113; terms given their broadest reasonable interpretation), may be prevented, (which again, given its broadest, reasonable interpretation), i.e., a material is ever kept from introduction into the system of a host, is doubted because the present claims merely recite a pharmacological composition while an effective prevention against the introduction of an infectious material into a host, especially where such material does not cause any pathology, would require that the exterior system of the host to be completely blocked so as to preclude any infectious material passing through such system and arriving within the system of the host.

In reading the present specification as a whole, it appears the tenor thereof is that infections, whether they cause a pathology or not, may be **inhibited** rather than be prevented. The former allowing at least one infectious material to pass into the system of the host rather than the latter which indicates that not even one of the infectious material is allowed to infect, i.e., pass into the system of the host.

As indicated above, the term "preventing" is here being interpreted as being synonymous with a circumstance such as where a vaccine is administered against a pathogen and the host to whom such was administered does not suffer from the pathogen's effect even when present in the host's system. As such the term "preventing" circumscribes a circumstance of almost absolute success. Because such success is not reasonably possible with the treatment of most infectious diseases/disorders, especially those having an etiology and pathophysiological manifestations as complex/poorly understood as encompassed by the present claims, the specification, which lacks an objective showing where prevention is actually manifest, is viewed as lacking an enabling disclosure of the same.

The Examiner notes that the term "prevent" is not *necessarily* synonymous with "cure" or the action of a vaccine, but such interpretation is proper given that "During patent examination, the pending claims must be 'given their broadest reasonable interpretation consistent with the specification.' *In re Hyatt*, 211 F.3d 1367, 1372, 54 USPQ2d 1664, 1667 (Fed. Cir. 2000). Applicant always has the opportunity to amend the claims during prosecution, and broad interpretation by the examiner reduces the possibility that the claim, once issued, will be interpreted more broadly than is justified. *In re Prater*, 415 F.2d 1393, 1404-05, 162 USPQ 541, 550-51 (CCPA 1969)." (MPEP § 2111).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RAYMOND HENLEY III whose telephone number is (571)272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey S. Lundgren can be reached on 571-272-5541. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Raymond J Henley III/
Primary Examiner
Art Unit 1629

August 19, 2011

EXHIBIT F

CLAIMS

I claim:

1. A method for electrostatically preventing harmful particulate matter from infecting an individual through nasal inhalation wherein a formulation is applied to skin or tissue of nasal passages of the individual in a thin film, said method comprising:
   a) electrostatically attracting the particulate matter to the thin film;
   b) holding the particulate matter in place by adjusting the adhesion of the thin film to permit said thin film to stick to the skin or tissue and by adjusting the cohesion of the formulation to provide adequate impermeability to the thin film; and,
   c) inactivating the particulate matter by adding at least one ingredient that would render said particulate matter harmless.
2. A formulation for electrostatically preventing harmful particulate matter from infecting an individual through nasal inhalation wherein the formulation is applied to skin or tissue of nasal passages of the individual in a thin film, said formulation comprising at least one cationic agent and at least one biocidic agent, and wherein said formulation, once applied:
   a) electrostatically attracts the particulate matter to the thin film;
   b) holds the particulate matter in place by adjusting the adhesion of the thin film to permit said thin film to stick to the skin or tissue and by adjusting the cohesion of the formulation to provide adequate impermeability to the thin film; and,
   c) inactivates the particulate matter and renders said particulate matter harmless.

EXHIBIT G

Interview Summary	Application No. 10/458,078	Applicant(s) ROLF, DAVID	
	Examiner Isis Ghali	Art Unit 1615	

All participants (applicant, applicant's representative, PTO personnel):

(1) *Isis Ghali*. (3)_____.

(2) *Mr. Gary Speier*. (4)_____.

Date of Interview: *24 May 2006*.

Type: a)☒ Telephonic b)☐ Video Conference
c)☐ Personal [copy given to: 1)☐ applicant 2)☐ applicant's representative]

Exhibit shown or demonstration conducted: d)☐ Yes e)☐ No.
If Yes, brief description: _____.

Claim(s) discussed: _____.

Identification of prior art discussed: _____.

Agreement with respect to the claims f)☐ was reached. g)☐ was not reached. h)☐ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: *Attorney indicated that no repose to the office action mailed 11/09/2005 has been filed*.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN A NON-EXTENDABLE PERIOD OF THE LONGER OF ONE MONTH OR THIRTY DAYS FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

Isis Ghali

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

Examiner's signature, if required

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record
A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews
Paragraph (b)
In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.
All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:
- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:
1) A brief description of the nature of any exhibit shown or any demonstration conducted,
2) an identification of the claims discussed,
3) an identification of the specific prior art discussed,
4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
5) a brief identification of the general thrust of the principal arguments presented to the examiner,
   (The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
6) a general indication of any other pertinent matters discussed, and
7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/458,078	06/10/2003	David Rolf	240.079US1	9269

21186 7590 11/09/2005

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH
1600 TCF TOWER
121 SOUTH EIGHT STREET
MINNEAPOLIS, MN 55402

EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 11/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/458,078	ROLF, DAVID	
	Examiner	Art Unit	
	Isis Ghali	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-87 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-87 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-87 are pending and included in the prosecution.

Specification

1. The use of the trademark "Vilmed" and "Q-15" has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

2. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA

1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1-87 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim21-30 of U.S. Patent No. 6,090,403. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims are directed to method for treating (or preventing) respiratory infection using patch comprising backing layer and formulation comprising essential oils positioned in or on the backing layer. The claims of the issued patent are directed to method for relieving cough or bronchial irritation using composition comprising essential oils on a foraminous carrier. It is anticipatory type double patenting rejection since the patented claims anticipate the present claims.

5. Claims 1-87 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-21 of copending Application No. 10/300,559. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims are directed to method for treating (or preventing) respiratory infection using patch comprising backing layer and formulation comprising essential oils positioned in or on the backing layer. The claims of the copending Application 10/300,559 are directed to patch

comprising essential oils positioned on or in a backing layer and used to treat bronchitis and asthma. Therefore, the present claims and the claims of the copending applications are directed to the same subject matter.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-81, 84, 85 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: the nature of the invention; the breadth of the claims; the state of the prior art; the relative skill of those in the art; the amount of direction or guidance presented; the predictability or unpredictability of the art; the presence or absence of working examples; and the quantity of experimentation necessary. When the above factors are weighed, it is the

examiner's position that one skilled in the art could not practice the invention without undue experimentation.

The nature of the invention: The nature of the invention is method for preventing respiratory infection using patch comprising essential oils. The specification does not enable the prevention of respiratory infection in susceptible patients.

The breadth of the claims: The claims are broad. The claims encompass prevention of respiratory infection in susceptible patients at risk, and the burden of enabling prevention of respiratory infection would be greater than that of enabling a treatment due to the need of additional testing and screening to those humans susceptible to such infection. The prevention of respiratory infection may or may not be addressed by the administration of the instant patch. Further, the claims encompass a wide class of essential oils and many respiratory infections.

The state of the prior art: The state of the art does not recognize the administration of essential oils to prevent respiratory infection as required in the instant claims. The state of the art recognizes the treatment of respiratory infection, but not its cure.

The relative skill of those in the art: The relative skill of those in the art is high.

The amount of direction or guidance presented: The guidance given by the specification on how to prevent the respiratory infection is absent. Guidance for treatment of respiratory infection is provided, however, no evidence that respiratory infection is prevented is provided. It is not obvious from the disclosure of treatment of respiratory infection using essential oils if the prevention of respiratory infection will be

achieved. A disclosure should contain representative examples which provide reasonable assurance to one skilled in the art that the compounds fall within the scope of a claim will possess the alleged activity. See *In re Riat et al.* (CCPA 1964) 327 F2d 685, 140 USPQ 471; *In re Barr et al.* (CCPA 1971) 444 F 2d 349, 151 USPQ 724.

The predictability or unpredictability of the art: The lack of significant guidance from the specification or prior art with regard to completely preventing respiratory infection by using the instant patch makes practicing the claimed invention unpredictable in terms of the prevention of the infection.

The presence or absence of working examples: No working examples to show preventing respiratory. Therefore, the specification has enabled treating respiratory infection, but not its prevention or cure.

The quantity of experimentation necessary: Therefor, the practitioner would turn to trial and error experimentation to practice the instant method for treating respiratory infection using the claimed patch without guidance from the specification or the prior art. Therefore, undue experimentation becomes the burden of the practitioner and as set forth the burden of enabling prevention of respiratory infection would be greater than that of enabling a treatment due to the need of additional testing and screening to those humans susceptible to such infection.

For examination purposes, the term "preventing" will be interpreted as "treating" respiratory infection.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 7, 46, 47, 67-69 and 78 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding to claim 7, the claim is confusing as it contains angina and mumps listed within the respiratory infections while these disorders are not respiratory infections. Angina is a thrombovascular disease caused by coronary arteries spasm or occlusion and not an infectious conditions. Mumps is infection of the salivary glands which is part of the digestive tract.

Claims 46, 47, 67-69 contain the trademark/trade name Vilmed and quat-15. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe fluorocarbon and preservative, accordingly, the identification/description is indefinite.

Regarding claim 78, the claim recite that "the source of essential oil is located within 6 inch of the mammal" and it is not clear what spot the patch will be 6 inch from?

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. Claims 1-8, 20-22, 32-37, 41-43, 71, 78-83 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 86/02270 ('270).

The present claim 1 recites treating respiratory infection using patch comprising an essential oil.

WO '270 discloses dressing comprising formulation for relieving cough comprising eucalyptus oil impregnated into a carrier of gauze, cotton or cloth and covered by a removable protective layer (page 4, lines 7-16; page 5, lines 17-20, 24). The dressing further comprising acrylate adhesive (page 5, lines 14-16). The essential oil is present in an amount ranging from 5-100% (page 6, lines 4-7). The formulation exerts its effect by the route of evaporation inhalation (page 3, lines 17-18). The formulation is effective against infection, bronchitis, and pneumonia (page 10, lines 4, 20, 25-27; page 11, lines 9-18).

12. Claims 1-15, 17-25, 28-37, 41-43, 59, 78-83 are rejected under 35 U.S.C. 102(b) as being anticipated by US 6,090,403 ('403).

The present claim 1 recites treating respiratory infection using patch comprising an essential oil.

US '403 discloses method to treat cold and cough using patch comprising essential oil the wherein the patch to be applied to the face, neck or chest to allow evaporated essential oils to be available to the natural inhalation through the nose or mouth (abstract). The patch comprising formulation comprising the essential oils and a carrier (col.2, lines 12-36). Essential oils included eucalyptus and peppermint (col.2, lines 61-65). The formulation further comprises 0.5-30% acrylic adhesive, 5-50% karaya gum, 44% glycerin (solvent), and water (col.3, lines 20-25; col.7, lines 63-67; col.8, lines 1-4, 15-20, 32-40). The carrier layer that can be porous to allow escape of the moisture or non-porous (col.2, lines 50-60). The carrier layer is typically a flexible sheet of open cell polyurethane foam, polyethylene, nonwoven fabric or cloth (col.4, lines 61-65).

13. Claims 1-9, 11-16, 19-22, 32-43, 52, 53, 61, 65, 71, 78-83 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,244,265 ('265).

The present claim 1 recites treating respiratory infection using patch comprising an essential oil.

US '265 discloses nasal strip or patch to treat cold and congestion comprising flexible backing and adhesive formulation comprising aromatic medication that can be

consumed by inhalation through the nose (abstract; col.4, lines 24-32; col.5, lines 44-47; col.16, lines 49-60). The adhesive formulation comprises acrylate or acrylic adhesive (col.7, lines 15-30). The formulation further comprising fragrance such as lemon fragrance, antiviral agents such as chloride containing agents, antimicrobial, vitamin E (col.5, lines 52-54; col.10, lines 15-17; col.11, lines 38-63, col.12, lines 1-3). Preferred aromatic medication is eucalyptus oil, peppermint oil and menthol (col.11, lines 19-25). The backing layer is porous permits the passage of air and moisture made of melt blown fibers of polyethylene or woven or nonwoven material and may contain fibers or material that improve resiliency (sizing agent) (col.7, lines 1-13, 58-67). The patch further comprising release liner (col.9, lines 13-15).

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15. Claims 9-19, 23-31, 38-40, 44-70, 72-77, 84-87 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO '270 in view of US 5,536,263 ('263).

The teachings of WO '270 are discussed above. However, WO '270 does not teach material of the backing, the amount of the adhesive, the solvent and its amount,

the karaya gum and its amount, the fragrance, the sizing agents, the skin protectant, the polyhydric alcohol, the additional antimicrobial agent, and the kit comprising mask.

The claimed amounts of different ingredients do not impart patentability to the claims, absent evidence to the contrary.

All the additional ingredients are well known in the art and it is within the skill in the art to use them in a conventional patch. The mask is known to deliver respiratory treatment.

US '263 teaches patch comprising porous flexible backing and formulation applied to the backing that solidify on the backing and permits sustained release comprising 3.3% eucalyptus oil, acrylic adhesive, solvent such as propylene glycol or glycerin, more than 20% karaya gum, and 0.2% quaternimum-15 (abstract; col.2, lines 2-9, 29-31; col.5, lines 26-28; col.6, lines 35-37; col.8, line 50-col.10, line 32). The backing comprising water-insoluble material and sizing agent, and is made of polyester fibers, cotton fibers, or cellulose fibers so it provides the required strength and integrity to the patch and conforms to the body contours therefore better tolerated by patients and more unobtrusive and allow moisture from the skin to evaporate to the atmosphere (col.1, lines 60-65; col.3, lines 1-29; col.5, lines 65-67). The patch further comprises a release liner (col.4, line 62).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to treat respiratory infection using patch comprising backing and formulation comprising essential oils as disclosed by WO '270 and add quat-15 and polyethylene glycol as disclosed by US '263 motivated by the teaching of US '263 that

composition comprising these ingredient provides sustained release of the active agent, and further replace the backing with a porous backing of fibers comprising sizing agent as disclosed by US '263, motivated by the teaching of US '263 that this kind of backing material provides the required strength and integrity to the patch and conforms to the body contours therefore better tolerated by the patient and more unobtrusive, with reasonable expectation of having patch comprising porous backing made of fibers of polyester and formulation comprising essential oils and quart-15 wherein the patch provides sustained release of the essential oils and has the required strength and integrity to conforms to the body contours wherein the patch is better tolerated by the patient and more unobtrusive.

16. Claims 16, 26, 27, 38-40, 44-58, 60-77, 84-87 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '403 in view of US '263.

The teachings of both references are discussed above. However, US '403 does not teach the backing made of fibers, the solvent and its amount, the fragrance, the specific sizing agents, the skin protectant, the polyhydric alcohol, the additional antimicrobial agent, and the kit comprising mask.

The claimed amounts of different ingredients do not impart patentability to the claims, absent evidence to the contrary.

All the additional ingredients are well known in the art and it is within the skill in the art to use them in a conventional patch. The mask is known to deliver respiratory treatment.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to treat respiratory infection using patch comprising backing and formulation comprising essential oils as disclosed by US '403 and add quat-15 and polyethylene glycol as disclosed by US '263 motivated by the teaching of US '263 that composition comprising these ingredient provides sustained release of the active agent, and further replace the backing with a porous backing of fibers comprising sizing agent as disclosed by US '263, motivated by the teaching of US '263 that this kind of backing material provides the required strength and integrity to the patch and conforms to the body contours therefore better tolerated by the patient and more unobtrusive, with reasonable expectation of having patch comprising porous backing made of fibers of polyester and formulation comprising essential oils and quart-15 wherein the patch provides sustained release of the essential oils and has the required strength and integrity to conforms to the body contours wherein the patch is better tolerated by the patient and more unobtrusive.

17. Claims 10, 17, 18, 23-31, 44-51, 54-60, 62-64, 66-77, 84-87 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '265 in view of US '263.

The teachings of both references are discussed above. However, US '265 does not teach the non-porous backing or the open cell foam backing, the amount of the adhesive, the solvent and its amount, the specific sizing agents, the polyhydric alcohol, the specific additional antimicrobial agent, and the kit comprising mask.

The claimed amounts of different ingredients do not impart patentability to the claims, absent evidence to the contrary.

All the additional ingredients are well known in the art and it is within the skill in the art to use them in a conventional patch. The mask is known to deliver respiratory treatment.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to treat respiratory infection using patch comprising backing and formulation comprising essential oils as disclosed by US '265 and add quat-15 and polyethylene glycol as disclosed by US '263 motivated by the teaching of US '263 that composition comprising these ingredient provides sustained release of the active agent, and further replace the backing with a porous backing of fibers comprising sizing agent as disclosed by US '263, motivated by the teaching of US '263 that this kind of backing material provides the required strength and integrity to the patch and conforms to the body contours therefore better tolerated by the patient and more unobtrusive, with reasonable expectation of having patch comprising porous backing made of fibers of polyester and formulation comprising essential oils and quart-15 wherein the patch provides sustained release of the essential oils and has the required strength and integrity to conforms to the body contours wherein the patch is better tolerated by the patient and more unobtrusive.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Isis Ghali
Examiner
Art Unit 1615

IG

EXHIBIT H

US006090403A

United States Patent [19]

Block et al.

[11] **Patent Number: 6,090,403**

[45] **Date of Patent: Jul. 18, 2000**

[54] **INHALATION THERAPY DECONGESTANT WITH FORAMINOUS CARRIER**

[75] Inventors: **Leslie L. Block**, Chaska; **David J. W. Goon**, Bloomington; **David Rolf**, Eden Prairie, all of Minn.

[73] Assignee: **LecTec Corporation**, Minnetonka, Minn.

[21] Appl. No.: **09/135,104**

[22] Filed: **Aug. 17, 1998**

[51] **Int. Cl.**[7] **A61L 15/16**; A61F 13/02

[52] **U.S. Cl.** **424/447**; 424/445; 424/448

[58] **Field of Search** 424/443, 445, 424/447, 448

[56] **References Cited**

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Primary Examiner—Carlos A. Azpuru

Attorney, Agent, or Firm—Schwegman, Lundberg, Woessner & Kluth P.A.

[57] **ABSTRACT**

A vaporizable decongestant is supported and stabilized on a flexible foraminous carrier composed typically of open-cell plastic foam, cloth or other fibrous material such as non-woven fabric. The term "foraminous" herein is intended to refer to a substance or medium containing minute openings or perforated by many minute apertures. The decongestant is placed on the surfaces within the interstices and minute apertures or on fibers from which the foraminous carrier is formed. Vaporization of the inhalable decongestant is facilitated by providing the potential for greatly increasing its exposed surface area. Distributing the decongestant composition over the large, expanded surface within the foraminous carrier is beneficial in enhancing both the volatilization and evaporation of the decongestant agent. It also prolongs the useful life of the product. Once vaporized, the aromatic decongestant is available for natural inhalation through the nose or mouth to help relieve one or more of the symptoms of cough, colds, nasal or chest congestion and related symptoms. The foraminous carrier is preferably provided in the form of a patch or sheet that is bonded to the skin to serve as a supporting base for the active decongestant agent. The patch defining the carrier is typically adhesively bonded to the upper part of the body, e.g. on the face, neck or chest, in a location where the decongestant is liberated into the air and can be inhaled through the mouth or nose.

41 Claims, 5 Drawing Sheets

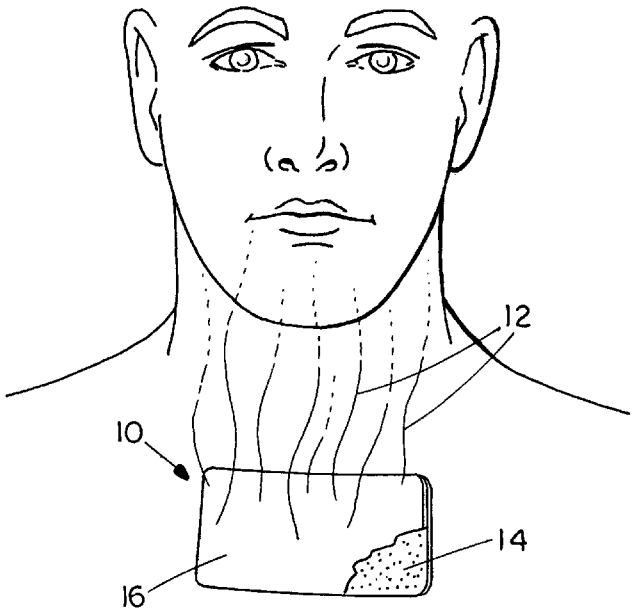


FIG. 1

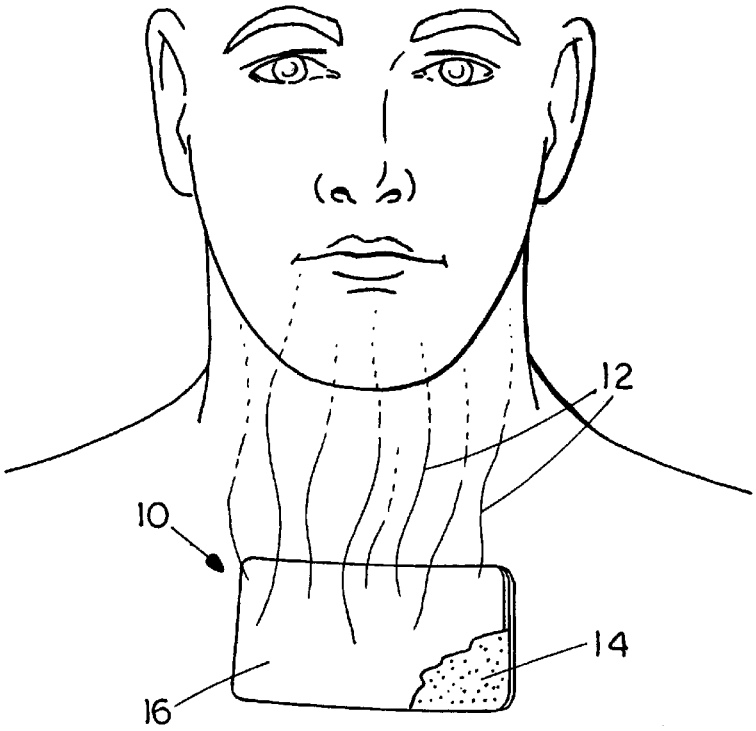


FIG. 2

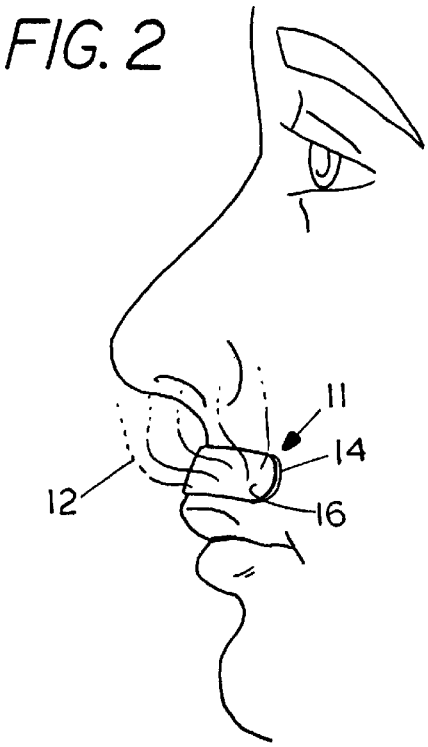


FIG. 3

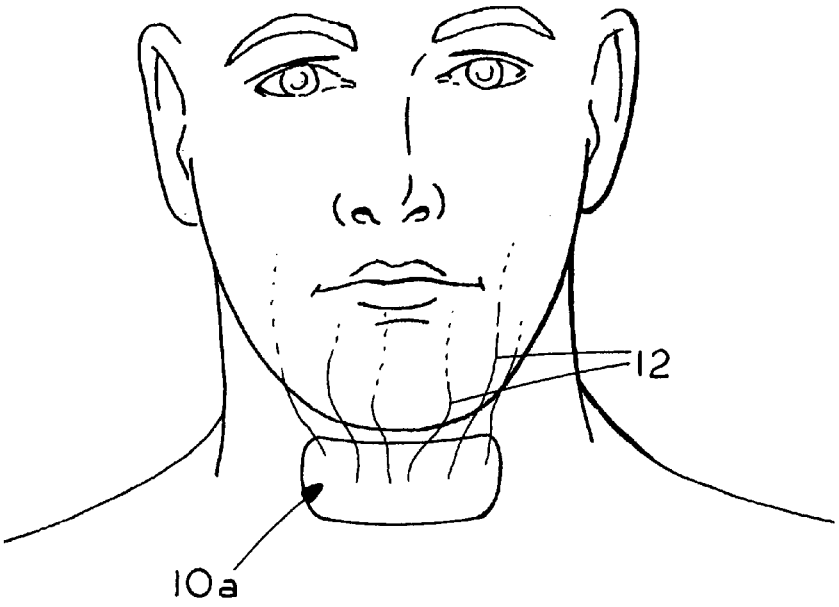


FIG. 4

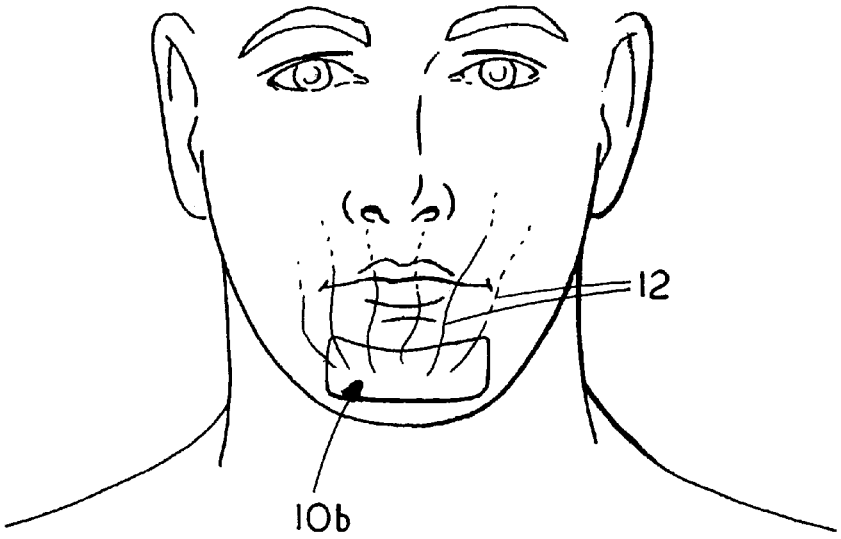


FIG. 5

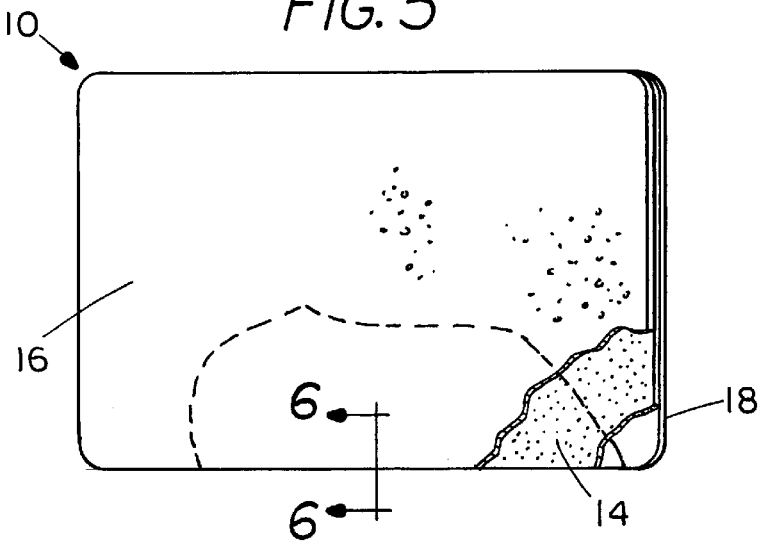


FIG. 6

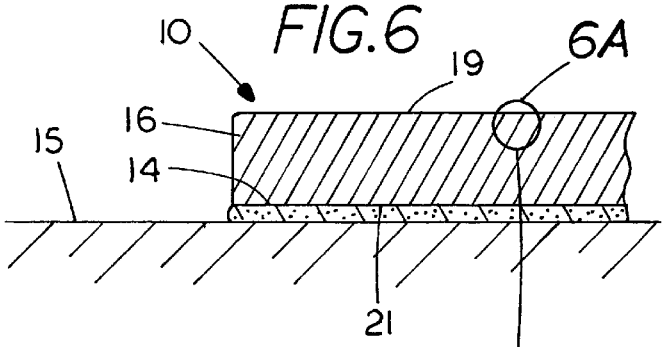


FIG. 6A

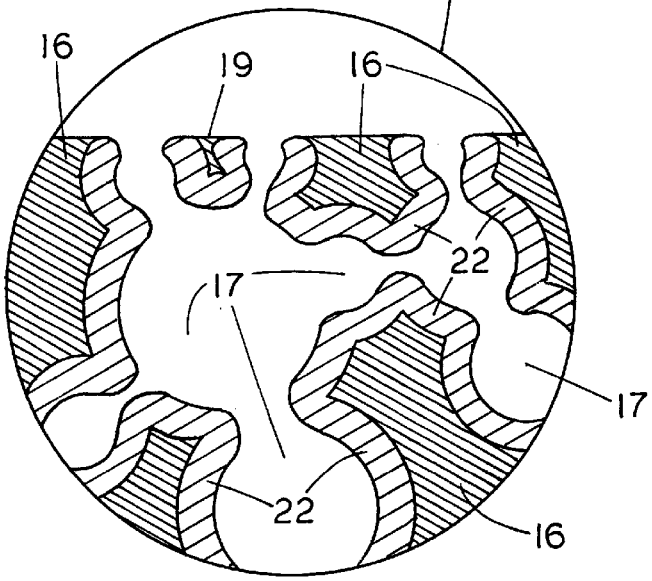


FIG. 7

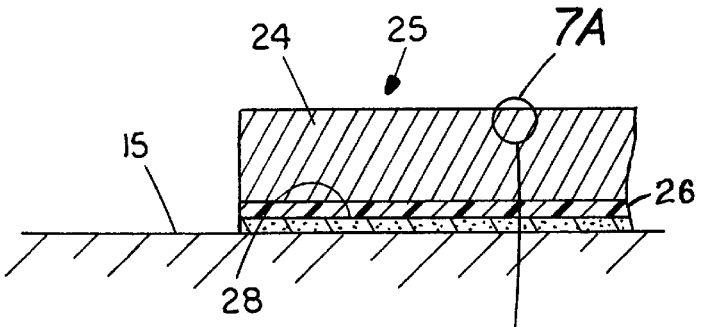


FIG. 7A

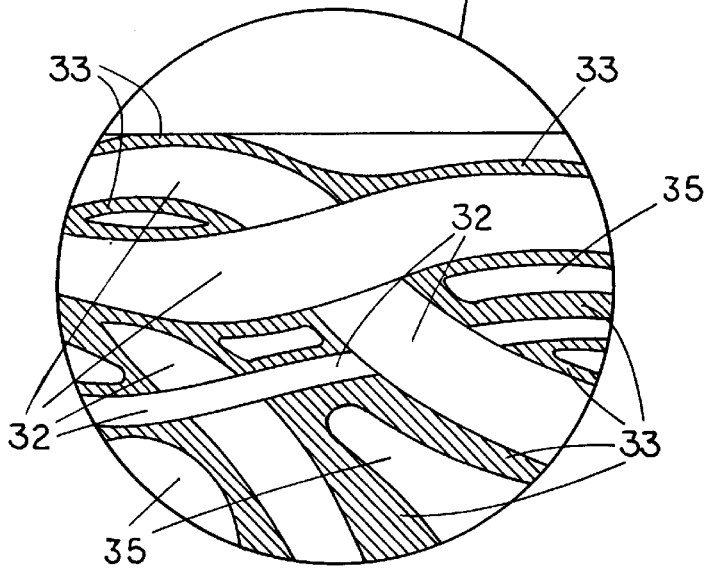
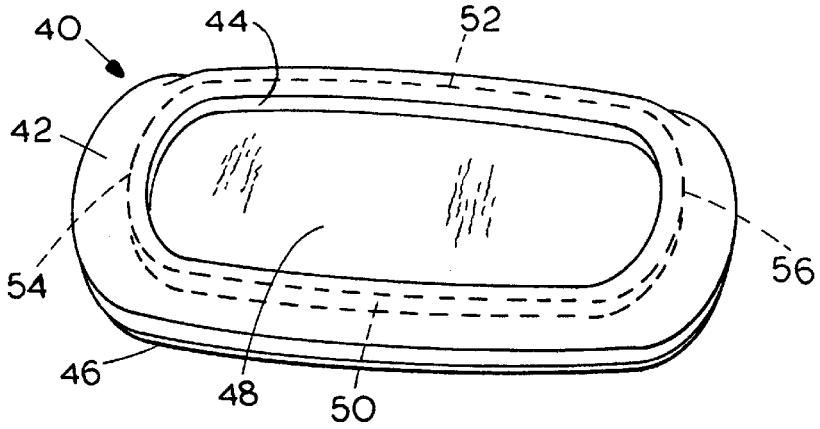


FIG. 8



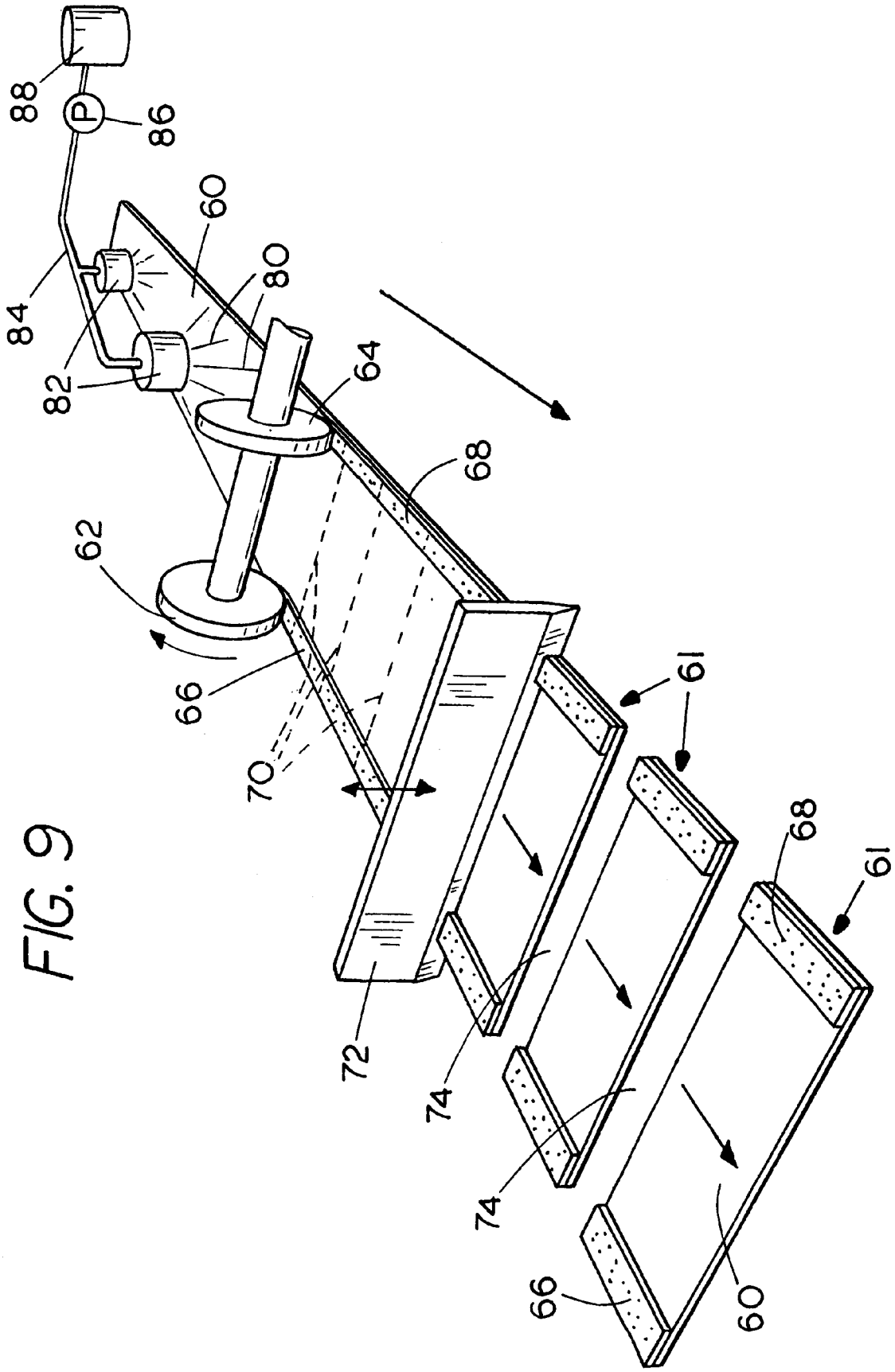


FIG. 9

INHALATION THERAPY DECONGESTANT WITH FORAMINOUS CARRIER

FIELD OF THE INVENTION

This invention relates to inhalation therapy and more particularly to the inhalation of decongestants for the relief of nasal congestion, cough, colds or chest congestion.

BACKGROUND OF THE INVENTION

About $1.5 billion per year are estimated to be spent in over-the-counter cold medications in the United States. Inhalation therapy employed for the relief of bronchial spasms, bronchial asthma, bronchitis, the relief of cough, colds and nasal congestion as carried out at the present time requires a pressurized can for expelling a given quantity of an aerosol containing a therapeutic agent such as epinephrine. These containers are expensive, require the patient to follow instructions carefully, and must be administered according to a set schedule. Other vaporizers that are sometimes used are even more complex. Electric nebulizers and hot water vaporizers are examples. In addition to the expense, these products cannot be used out of doors or away from home. Consequently, they are unsuitable for use at the work place or while riding in a car. Because of these problems, decongestants such as camphor which are intended to be applied to the throat and chest are sometimes used to help relieve cough or cold symptoms. A decongestant of this type typically has a petrolatum base, giving it the consistency of petroleum jelly. One such product is sold under the trademark VICK'S VapoRub®. A similar topical aromatic composition is described in U.S. Pat. No. 5,322,689 but without a high level of petrolatum. Instead, a carboxylic acid copolymer is used. This composition, however, has the consistency of a fluid like the VICK'S product and is also applied topically. These products have significant drawbacks. Petroleum-based fluids are greasy and tend to be spread onto areas that are not intended. In addition, the fingers of the user must be dipped into the fluid product and, consequently, the product gets onto hands, on clothing, and can even be spread to areas where it can cause irritation, such as the nasal mucosa or the eyes. When applied by a healthcare worker, the smell of the decongestant can be carried away on hands and clothing. Moreover, because of the fluidity of such these products, they soon rub off onto the user's clothing and bed linens.

Another shortcoming of prior decongestants is the limitation on the rate of evaporation of the active aromatic substances. A large portion lies beneath the surface and is therefore not exposed to the air. The vaporization of this sub-surface material is therefore inhibited. One object of the present invention is to overcome this deficiency by finding a way to promote volatilization of active decongestant agents.

In view of these and other deficiencies of the prior art, it is one object of the present invention to provide a decongestant for alleviating one or more of the symptoms of nasal congestion, cough, colds or bronchial congestion but which is also comfortable to use, non-greasy and can be easily and quickly removed from the skin when no longer needed.

Another object is to provide an oral and nasal decongestant which readily evolves decongestant vapor that can be inhaled through the mouth or nose but will not spread out on the skin or be accidentally transferred to clothing.

Still another object of the invention is to provide an improved decongestant which readily diffuses into the air but still provides therapeutic effects that are long lasting.

A further object is to provide an improved decongestant and carrier for inhalation therapy which if desired can be structured to also provide analgesic effects through the skin.

These and other more detailed and specific objects of the present invention will be better understood by reference to the following figures and detailed description which illustrate by way of example of but a few of the various forms of the invention within the scope of the appended claims.

SUMMARY OF THE INVENTION

The present invention provides a decongestant, preferably an aromatic, vaporizable decongestant supported on a foraminous carrier composed typically of an open-cell plastic foam, perforated plastic film, cloth or other fibrous material such as nonwoven fabric. The term "foraminous" herein is intended to refer to a substance or medium containing minute openings or perforated by many minute apertures. To form such a product in accordance with the present invention, an inhalable decongestant is placed on surfaces within the interstices and minute apertures or on fibers of which the foraminous carrier is composed. In this way vaporization of the inhalable decongestant is facilitated by providing the potential for greatly increasing its exposed surface area. Thus, distributing the decongestant composition over the large, expanded surface within the foraminous carrier is beneficial in enhancing both the volatilization and evaporation of the decongestant agent. It also helps to prolong the useful life of the product. Once vaporized, the aromatic decongestant is available for natural inhalation through the nose or mouth to help relieve one or more of the symptoms of cough, colds, nasal or chest congestion and related symptoms. The foraminous carrier is preferably provided in the form of a patch or sheet that is bonded to the skin and acts as a supporting base for the active decongestant agent.

The patch defining the carrier is placed on the upper part of the body, typically on the face, neck or chest, in a location where the decongestant is liberated into the air and can be inhaled through the mouth or nose. The patch which serves as a carrier for the decongestant is bonded to the skin either through the provision of an adhesive on the lower surface of the patch or by means of a separate piece of pressure-sensitive adhesive tape or adhesive coating, either surrounding the carrier or applied along the edges of the lower surface of the carrier.

The decongestant can be applied to the foraminous carrier in various ways. For example, by spraying, roll-coating, dipping, knife-coating, or calendering. If desired, the decongestant agent can extend substantially through the entire thickness of the carrier sheet. It is preferred that the entire patch be non-occlusive, i.e. capable of allowing moisture from the skin to diffuse outwardly and escape through the upper surface of the patch. However, if desired, the foraminous carrier sheet can be provided as an upper layer of the patch which is bonded to a non-porous sheet material such as a sheet of plastic film having a separate layer of pressure-sensitive adhesive on its lower surface for bonding the patch to the skin. In this case, the patch as a whole is occlusive and as such will not allow moisture to escape from the skin.

A variety of well known therapeutic agents that have a decongestant or analgesic action can be employed. Examples include oil of wintergreen, menthol, thymol, camphor, oil of peppermint, eucalyptus oil, phenylephrine hydrochloride, pheniramine maleate, benzalkonium chloride, methyl salicylate, pseudoephedrine hydrochloride, oxymetazoline hydrochloride, xylometazoline

hydrochloride, methazoline hydrochloride, epinephrine, spirits of turpentine, ephedra (ma huang), coltsfoot (*Tussilago farfara L.*), ginger (*Zingiber officinale*), naphazoline hydrochloride, and other decongestants known in the art. We have found that the turpentine, because of its volatility, appears to help co-evaporate other active decongestant agents. To prepare the patch, the decongestant, i.e. the therapeutic agent, is preferably dispersed in a vehicle to form an ointment that can either be hydrophilic or hydrophobic in nature. A typical hydrophilic vehicle preferably includes a thickener comprising a water-dispersible or water-swellable natural or synthetic polymer. The thickener raises the viscosity to a level that resists spreading and can, if desired, cause the ointment to set-up as an elastic solid. A hydrophilic ointment also contains water and a humectant such as a polyhydric alcohol. Typical hydrophobic vehicles comprise mineral oil or petroleum jelly, or a combination thereof, in which decongestant agents are dispersed or dissolved. Another hydrophobic vehicle comprises a pressure-sensitive adhesive matrix such as a dispersion of natural or synthetic rubber, an oleaginous plasticizer such as mineral oil, and a tackifying resin such as a terpene resin. Other adhesives can be used, such as vinyl emulsion adhesives, acrylic polymeric adhesives, vinyl acetate copolymers or silicone adhesives. Other medical adhesives which can be used will be apparent to those skilled in the art.

When the decongestant agents are mixed with the vehicle, an ointment is produced. The ointment is then stabilized by applying it to the greatly expanded surface area within the minute apertures and interstices between the fibrils, perforations and/or pores of the foraminous carrier. This, together with a thickening agent that can, if desired, be contained in the ointment, gives the ointment sufficient body, support and stability to hold it in place and prevent it from becoming smeared onto fingers, clothing, bed linens or onto other parts of the body where one or more of the decongestant agents could cause irritation, such as nasal mucosa or the eyes. In addition, the foraminous carrier supporting the decongestant enables all of the decongestant material to be easily and quickly removed when no longer needed with little or no residue left on the skin. In addition, by distributing the ointment over the extended surface of the foraminous carrier, more of the decongestant can be exposed to the air. The much greater exposed surface area facilitates evaporation of the decongestant, thus allowing more of the active agents it to be inhaled so as to improve the reduction of nasal or chest congestion and related cold and sinus symptoms.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a perspective view showing the invention in use on the chest.

FIG. **2** is a perspective view showing use of the invention between the upper lip and nose.

FIG. **3** is a perspective viewing showing use of the invention on the neck.

FIG. **4** is a perspective view showing the use of the invention on the chin.

FIG. **5** is a greatly enlarged plan view of the invention.

FIG. **6** is a cross-sectional view of the invention taken on line **6**—**6** of FIG. **5**.

FIG. **6A** is a microscopic cross-sectional view of FIG. **6**.

FIG. **7** is a cross-sectional view of another form of carrier.

FIG. **7A** is a microscopic view of FIG. **7** showing the active decongestant distributed on the extended surface of the foraminous carrier.

FIG. **8** is a perspective view of the invention in which medical adhesive tape is used to bond the carrier to the skin, and

FIG. **9** is a perspective view showing the application of adhesive along the edges of decongestant patches embodying the invention.

DETAILED DESCRIPTION OF THE INVENTION

Refer now to the figures in which the same numbers refer to corresponding parts in the several views, and particularly to FIGS. **1** and **5** which illustrate generally rectangular patch **10** that is applied to the upper chest area of a patient. The patch **10** includes an upper flexible foraminous decongestant-supporting carrier sheet **16** and is particularly advantageous for improving symptoms of chest congestion. The patch **10** provides for the evaporation of decongestant indicated diagrammatically at **12** which can then be inhaled by the patient through the nose or mouth. The warming of the patch **10** by the skin after the patch **10** has been applied helps to increase the rate of evaporation of the decongestant vapors **12**. The patch **10** in this case is provided with an underlying layer of medical grade, non-irritating pressure-sensitive adhesive **14** of any suitable type known to those skilled in the art, for example as described in U.S. Pat. Nos. 5,536,263; 4,675,009; 2,498,338; 3,645,835; 4,427,737 and 4,867,150 which are incorporated herein by reference for bonding the patch to the skin. The lower surface of adhesive **14** is protected during shipment and storage by a removable liner sheet **18** (FIG. **5**) that can comprise any suitable commercially available release paper or plastic film. Before use, the liner sheet **18** is removed to expose the lower surface of the pressure-sensitive adhesive **14**. The patch **10** is then applied to the skin and is held in place by the pressure-sensitive adhesive, for example, on the upper chest area of the patient as shown in FIG. **1**.

Overlying the pressure-sensitive adhesive **14** and bonded to it is the foraminous carrier **16** to which an ointment containing a decongestant is applied. If desired, the pressure-sensitive adhesive **14** can have the same composition as the ointment. In such a case, the pressure-sensitive adhesive **14** can also contain a therapeutic medicament comprising a decongestant and/or analgesic agent. It will then be possible for the decongestant or analgesic to be absorbed into the skin to provide a therapeutic effect by absorption into the underlying tissue to achieve localized relief for the symptoms of bronchial congestion. The invention is thus capable of providing a therapeutic effect in two ways simultaneously; namely, by dermal absorption into the skin as well as by inhalation of the decongestant vapors via the mouth or nose. In this way the invention can provide a dual therapeutic action. If the pressure-sensitive adhesive **14** is of a different composition from the ointment, for example an ordinary, non-irritating medical grade rubber-based adhesive, then the patch **10** will have but a single mode of operation; namely, the evolution of the aromatic decongestant vapor **12** for providing inhalation therapy. The patch **10** for use on the chest is typically about 3 inches long by 2 inches wide and has rounded corners. The foraminous carrier sheet typically has a thickness of about 3–8 mils and contains about 0.012 ounces per square inch of the decongestant-containing ointment. The foraminous carrier **16** is typically a flexible sheet of open-cell polyurethane foam, open-cell polyethylene foam, nonwoven fabric or cloth.

Refer now to FIG. **2** which illustrates slightly curved patch **11** applied to the nasolabial area of a user just below

the nose. The patch **10** is particularly advantageous for improving symptoms of nasal congestion or cough by providing for the evaporation of decongestant indicated diagrammatically at **12** into the air, which can then be inhaled by the patient through the nose. The patch **11** has a foraminous upper carrier layer **16** to which the decongestant-containing ointment is applied. The patch **10** also includes an underlying layer of non-irritating medical grade pressure-sensitive adhesive **14** of any suitable type known to those skilled in the art, for example as described above in connection with FIGS. **1** and **5**. The adhesive **14** is protected during shipment and storage by a removable liner sheet (not shown) similar to **18** in FIG. **5** that can comprise any suitable commercially available release paper or plastic film. The pressure-sensitive adhesive **14** bonds the foraminous carrier **16** and the decongestant contained therein in place above the upper lip of the patient just below the nose as shown in FIG. **2**.

The patch **11** for use between the upper lip and nose is typically about 2 inches long by ¾ inches wide and has rounded corners. The foraminous carrier sheet typically has a thickness of about 3–8 mils and contains about 0.012 ounces per square inch of the decongestant-containing ointment. The foraminous carrier **16** can comprise a sheet of open-cell foam plastic, such as a flexible sheet open-cell polyurethane foam, open-cell polyethylene foam, nonwoven fabric or cloth.

Refer now to FIGS. **3** and **4** which illustrate generally rectangular patches **10***a* and **10***b* applied to the neck and chin, respectively. The patches **10***a* and **10***b*, which have the same construction described in connection with FIGS. **1** and **5** but are smaller, are especially useful for improving symptoms of head congestion. Both provide for the evaporation of decongestant into the air as indicated diagrammatically at **12**. The vapor can then be inhaled by the patient through the nose or mouth. The construction of the patches **10***a* and **10***b* is the same as described above. The neck patch **10***a* of FIG. **3**, however, has the decongestant ointment exposed on its lower surface and the ointment contains an adhesive material. Thus, the ointment provides an analgesic effect through dermal absorption, which is useful in relieving the symptoms of cough and itchy throat.

The patch **10***a* or **10***b* for use on the neck or chin is typically about 3 inches long by 2 inches wide and has rounded corners. The overall thickness can be about 5–22 mils and contains about 0.012 ounces per square inch of the decongestant-containing ointment. The foraminous carrier **16** can comprise a sheet of polyurethane foam, cloth or nonwoven fabric. The chin patch is especially advantageous for providing decongestant vapor for oral inhalation.

Refer now to FIGS. **6** and **6A** which illustrate cross-sectional views of the invention as it appears when applied to the skin **15** of a patient after removal of the liner sheet **18**. The foraminous decongestant carrier **16** comprises an upper layer and the pressure-sensitive adhesive **14** comprises a lower layer. The foraminous carrier **16** contains openings or foramina **17** throughout which communicate between the upper and lower surfaces **19** and **21** of the foraminous carrier **16**. This allows moisture from the skin **15** to escape through the patch **10**. Applied to the surfaces lining the apertures and interstices **17** within the foraminous carrier **16** is a quantity of an ointment **22** containing the active aromatic decongestant agent. Support by the carrier **16** makes possible a greatly extended exposed surface due to the multiplicity of minute foramina **17** within the carrier **16**. The increased extended surface area of the ointment within the carrier **16** makes possible much improved volatilization of the aromatic decongestant contained in the ointment, thereby enhancing the liberation of vapor into the air for inhalation therapy through the nose or mouth.

In the patch **10** of FIGS. **6** and **6A**, the pressure-sensitive adhesive layer **14** has the same composition as the ointment **22** which contains both the active decongestant and a suitable adhesive and thickener such as a natural or synthetic polymeric adhesive or gum dispersed in the ointment **22**.

Refer now to FIGS. **7** and **7A** which illustrate a modified form of the invention. In FIG. **7**, a foraminous carrier sheet designated **24** comprises a fibrous sheet formed from non-woven cotton fabric containing microscopic fibers **32** (FIG. **7A**) which are bonded together at their points of contact. A typical foraminous carrier is a flexible sheet about 5 mils thick. Applied within the foramina **35** to the surfaces of the fibers **32** is a decongestant ointment **33**. Bonded to the lower surface of the foraminous carrier **24** by the ointment is a barrier such as a sheet of plastic film, e.g. 2 mil. polyester film **26**. Applied as a coating on the lower surface of the polyester film **26** is a layer of commercially available medical grade non-irritating pressure-sensitive adhesive **28** that bonds the patch **25** to the skin **30**. The foraminous carrier layer **24** comprises a fibrous mass of intersecting fibers **32** (FIG. **7A**) to which the ointment **33** is applied. The microscopic fibers **32** provide an extremely high surface area. This can give the applied ointment **33** containing the active decongestant agent a greatly extended surface area which, as already noted, helps to volatilize the decongestant thus making it more available for inhalation therapy so as to provide greater effectiveness in the relief of the symptoms of cough, colds, nasal congestion or chest congestion. At the same time, the foraminous carrier **24** stabilizes the ointment by holding it in place and keeping the ointment it from spreading onto other parts of the body, the clothing, bed linens, etc. In this embodiment, the ointment **33** contains a thickener that helps the ointment set or gel once applied to the foraminous carrier **24**. For this purpose, we employ a high molecular weight natural or synthetic polymer and optionally a polymeric adhesive as a part of the ointment. Accordingly, the upper portion of the patch **25** can be thought of as a stabilized ointment containing a vaporizable decongestant that is spread over an extended surface of the solid but flexible foraminous carrier **24**.

The form of the invention shown in FIGS. **7** and **7A** has an important advantage since the decongestant contained in the foraminous carrier **24** does not contact the skin. This benefits some people, particularly those with sensitive skin and children, who sometimes complain about the tingling or burning sensation that is noticed when certain decongestants are placed in direct contact with the skin.

Refer now to FIG. **8** which illustrates a decongestant patch **40** in accordance with the invention that is held in place on the skin by means of a sheet of medical grade adhesive tape **42** having an opening **44** cut in its center. The adhesive tape **42** is elongated and has rounded corners. The adhesive tape **42** can be any suitable commercially available medical adhesive tape having an adhesive layer **46** on its lower surface for bonding the patch **40** to the skin and for bonding the adhesive tape **42** to the edge of a flexible foraminous carrier sheet **48** which typically comprises a sheet of plastic foam, fibrous material such as woven or nonwoven plastic or gauze saturated with an aromatic decongestant. The foraminous carrier **48** has side edges **50**, **52** and end edges **54**, **56** which are all bonded in place by the inner edge of the adhesive tape **42** adjacent the opening **44**. It will be understood that the foraminous carrier sheet **48** itself has no adhesive and depends entirely upon the adhe-

sive tape **42** to hold it in place on the skin. The patch **40** can be made in any suitable size and positioned conveniently on the skin wherever desired so that the decongestant vapors when given off can be inhaled through the mouth or nose during normal respiration.

Refer now to FIG. **9** which illustrates the application of adhesive bands on opposed edges of the invention for securing the flexible foraminous carrier to the skin. In FIG. **9**, the foraminous carrier **60** which comprises a strip of fabric passes from right to left in the figure beneath adhesive applicator rolls **62**, **64** which rotate in a given feed direction to apply strips of adhesive **66**, **68** along parallel opposed edges of the carrier **60**. Pressure-sensitive adhesive (not shown) is applied continually to the rolls **62**, **64** to keep the surface of the rolls **62**, **64** coated with adhesive. The foraminous carrier sheet **60** is periodically cut transversely in any suitable manner along separation lines indicated at **70** by a cutter such as a reciprocating blade **72** which severs the carrier sheet **60** transversely at spaced apart locations indicated at **74** to provide finished patches **61** with pressure-sensitive adhesive strips **66**, **68** along opposed edges. The carrier sheet **60** can be of any of the compositions described above. Prior to passing beneath rolls **62**, **64**, a vaporizable decongestant agent **80** of a suitable composition is applied as a spray by means of spray heads **82** to which the decongestant is pumped under pressure through a feed line **84** by means of pump **86** from supply tank **88**. The spray of decongestant material **80** impinges upon the carrier sheet **60** so as to coat the fibers that line the openings or foramina within the foraminous structure of the carrier **60**. If desired, heat can be applied to the sheet **60** to drive off excess moisture and to help thicken the decongestant **80** that has been applied by the spray heads **82**. The decongestant is then supported and stabilized by the foraminous structure of the carrier **60** and, if desired, by a thickening agent contained in the decongestant as described above. The patches **61** are used in the same manner as described above and can be made in any convenient size. In this case the decongestant spray **80** itself contains no adhesive since the patches **61** will be adequately bonded to the skin by means of the pressure-sensitive adhesive strips **66**, **68**.

For various applications, the patches can measure from about 2 inches by 3 inches to about 4 inches by 5 inches, or larger, for application to the chin, neck or chest. When the patch is applied to the nasolabial area just beneath the nose, it can be about 2¾ inches long by ⅜ inches wide with a slight concave upper edge if desired. The patches can be made in other sizes and shapes to fit the portion of the body to which they are applied.

The ointment is prepared by mixing together a vehicle preferably containing a polymeric thickener, either with water or non-polar solvent as the case may be, and a pre-mix containing the active decongestant agent. If the ointment is formed with an aqueous base, a preferred thickener comprises a hydrophilic polymer that is either soluble in water or will swell in contact with water. A humectant such as a polyhydric alcohol is also advantageously employed. The method used for mixing the ointment can be similar to the method used for preparing the medication-containing reservoir described in U.S. Pat. No. 5,536,263 which is incorporated herein by reference.

One preferred form of ointment contains the following: about 0.1% to about 10% camphor; about 0.5% to about 5% menthol; about 0.1% to about 5% eucalyptus oil; about 0.5% to about 10% spirits of turpentine; about 10% to about 60% of a humectant of which a polyhydric alcohol such as glycerin or propylene glycol are examples; and a thickener comprising a natural or synthetic polymeric gum such as karaya or polyacrylamide is provided in the amount of about 5% to about 50%. The active decongestant is preferably prepared as a pre-mix by blending ingredients together in a suitable mixer and then admixing the pre-mix to the ingredients present in the vehicle. All quantities herein are presented as percent by weight unless otherwise specified.

A variety of other natural or synthetic gel-forming polymers can be used as a thickener in place of karaya or polyacrylamide. These include gum acacia, locust bean gum, guar gum, modified guar gum, maltodextrin, carboxymethyl cellulose, carboxypropyl cellulose, and polyacrylic acid. Optionally, a water dispersible adhesive is provided, such as a carboxylic acid polymer, e.g. Carbotac™ 26222 or 26171 by the B. F. Goodrich Company of Cleveland, Ohio, in the amount of about 0.5% to about 30%. The adhesive, however, can be any suitable non-irritating medical grade adhesive including adhesives such as acrylate emulsion adhesive, acrylic ester copolymer adhesives, vinyl acetate resins, and copolymers of vinyl acetate and dioctyl maleate and the like. Other pressure-sensitive adhesives can be employed such as silicone pressure-sensitive adhesives prepared as described in U.S. Pat. Nos. 3,627,851; 3,772,247; 2,736,721 and 2,814,601 each of which is incorporated herein by reference. Still other pressure-sensitive adhesives that can be used are described in U.S. Pat. No. 2,857,356 which is also incorporated herein by reference. Additional adhesives which can be used are described as adhesives for transdermal delivery devices in U.S. Pat. Nos. 4,951,657; 4,655,767 and 5,232,702 which are all incorporated herein by reference.

One preferred ointment comprises about 6% camphor; about 3% menthol; about 1% eucalyptus oil; about 4% spirits of turpentine; about 44% glycerin; about 1% aloe vera; a thickener comprising about 34% karaya gum; and about 7% of a water-borne latex adhesive such as a carboxylic acid polymeric adhesive, e.g. 2 parts Carbotac™ 26222 and 1 part Carbotac™ 26171. The ointment can be applied to the foraminous carrier either by roll-coating or by knife-coating without dilution or, if applied by spraying or dipping, it can be diluted with an equal amount of water. After being applied, the ointment is then preferably heated, e.g. to between about 120° F. and 150° F. to help drive off excess moisture and to assist in setting the structure of the ointment within the minute foramina of the carrier. This distribution of the decongestant promotes volatilization and evaporation of the active decongestant agent and helps to keep the ointment where it is placed. It also allows it to be cleanly removed from the skin when no longer needed.

The invention has been well received by users because it prevents clothes and fingers from becoming smeared with ointment, while holding the ointment in place where the decongestant vapors will be readily available for inhalation. The invention is also capable of distributing the ointment over the relatively large extended surface of the foraminous carrier to aid in promoting the transfer of the decongestant from the solid state to the vapor state. The invention also enables the decongestant vapor to be reliably evolved over a relatively long period of time, e.g. up to eight or more hours, and was therefore adjudged long-lasting by the average user. In addition, the invention enables the decongestant to act in a dual capacity; namely, both as a vaporous inhalant and also as an analgesic through dermal absorption into the capillaries beneath the skin surface. The decongestant-containing patches have proved effective in the temporary relief of coughs due to colds, minor throat and bronchial irritation, and temporarily suppresses cough occurring with

a cold. When used on the chest, the invention temporarily relieves cough due to colds, minor throat and bronchial irritation and temporarily suppresses cough occurring with a cold. On the chest it can also act as a topical analgesic to relieve minor aches and pains in the chest area via dermal absorption through the skin. The decongestant patches of the present invention are comfortable, non-greasy and easy to apply with little, if any, traces of greasy material being left after removal or transferred to the fingers, clothes or bed linens. The decongestant agents are readily vaporized, and the patch as a whole can be made non-occlusive so as to eliminate the possibility of perspiration becoming trapped beneath the patch. The patches can be made so as to keep the decongestant agent away from the skin to prevent possible irritation. The invention also helps people without cold symptoms to sleep better by making it possible for one to breathe easily through the nose throughout the entire night. The invention is therefore also a sleep aid. Finally, the inhalable decongestants do not appear to interact with other medications that may be taken by the patient.

The finished patches are preferably packaged in envelopes or boxes with instructions to apply them to the upper part of the body; namely, the nasolabial area, the chest, the chin, and the throat.

Many variations of the present invention within the scope of the appended claims will be apparent to those skilled in the art once the principles described herein are understood.

What is claimed is:

1. A skin patch for the relief of the symptoms of cough, colds, nasal congestion or chest congestion, comprising,

symptomatic cold reliever supported upon a non-occlusive flexible foraminous carrier and means operatively associated with the carrier for securing the carrier to the skin surface to enable said symptomatic cold reliever to be available for natural inhalation during respiration through the mouth or nose;

wherein the skin patch is free of a 5-substituted furan methyl ketone.

2. The skin patch of claim **1** wherein the symptomatic cold reliever is an ointment containing an active agent selected from the group consisting of oil of wintergreen, menthol, thymol, camphor, oil of peppermint, eucalyptus oil, phenylephrine hydrochloride, pheniramine maleate, benzalkonium chloride, methyl salicylate, pseudoephedrine hydrochloride, oxymetazoline hydrochloride, xylometazoline hydrochloride, methazoline hydrochloride, epinephrine, spirits of turpentine, ephedra (ma huang), coltsfoot (*Tussilago farfara L.*), ginger (*Zingiber officinale*), and naphazoline hydrochloride.

3. The skin patch of claim **1** wherein the symptomatic cold reliever is dispersed in an ointment including as a thickener a natural or synthetic gel-forming polymer comprising a member selected from the group consisting of gum karaya, gum acacia, locust bean gum, guar gum, modified guar gum, maltodextrin, carboxymethyl cellulose, carboxypropyl cellulose, polyacrylamide, and polyacrylic acid.

4. The skin patch of claim **1** wherein the symptomatic cold reliever is dispersed in a vehicle that includes a resin emulsion adhesive.

5. The skin patch of claim **1** wherein said means comprises an adhesive selected from the group consisting of acrylate emulsion adhesive, an acrylic ester copolymer, a vinyl acetate resin, a copolymer of vinyl acetate and dioctyl maleate, silicone adhesive, natural or synthetic rubber, a petroleum derivative, and a resin.

6. The skin patch of claim **3** wherein the symptomatic cold reliever is dispersed in a vehicle which includes a humectant comprising a polyhydric alcohol.

7. A skin patch, comprising,

a patch body including a flexible foraminous carrier sheet having a multiplicity of minute foramina extending therethrough to provide an extended surface,

an ointment containing a symptomatic cold reliever,

said ointment being distributed upon the extended surface of the foramina within the carrier for supporting and stabilizing the ointment and to promote volatilization and evaporation of the symptomatic cold reliever for inhalation through the nose or mouth to relieve of one or more of the symptoms of cough, cold, nasal congestion, or chest congestion.

8. The skin patch of claim **7** wherein a pressure-sensitive adhesive is exposed on the lower surface of said skin patch for bonding the patch to the skin of a patient.

9. The skin patch of claim **7** wherein said ointment contains a symptomatic cold reliever selected from the group consisting of oil of wintergreen, menthol, thymol, camphor, oil of peppermint, eucalyptus oil, phenylephrine hydrochloride, pheniramine maleate, benzalkonium chloride, methyl salicylate, pseudoephedrine hydrochloride, oxymetazoline hydrochloride, xylometazoline hydrochloride, methazoline hydrochloride, epinephrine, spirits of turpentine, ephedra (ma huang), coltsfoot (*Tussilago farfara L.*), ginger (*Zingiber officinale*), and naphazoline hydrochloride.

10. The skin patch of claim **7** wherein the ointment includes a thickener comprising a natural or synthetic gel-forming polymer selected from the group consisting of gum karaya, gum acacia, locust bean gum, guar gum, modified guar gum, maltodextrin, carboxymethyl cellulose, carboxypropyl cellulose, polyacrylamide, and polyacrylic acid.

11. The skin patch of claim **7** wherein the ointment includes a resin emulsion adhesive.

12. The skin patch of claim **7** wherein the ointment includes an emulsion adhesive comprising a member selected from the group consisting of acrylate emulsion adhesive, an acrylic ester copolymer, a vinyl acetate resin, a copolymer of vinyl acetate and dioctyl maleate, and silicone adhesive.

13. The skin patch of claim **10** wherein the ointment includes a humectant comprising a polyhydric alcohol.

14. A skin patch, comprising,

a flexible laminate for being bonded to the skin of a patient,

said laminate including a vehicle containing a symptomatic cold reliever on at least an upper portion thereof,

a carrier for the vehicle comprising a sheet of flexible foraminous material to support the vehicle, and

a pressure-sensitive adhesive exposed on a lower surface of said patch for bonding the patch to the skin of a patient wherein the skin patch is free of a 5-substituted furan methyl ketone.

15. The skin patch of claim **14** wherein the pressure-sensitive adhesive is a layer of adhesive material applied to a lower surface of said skin patch for bonding the patch to the skin of a patient.

16. The skin patch of claim **14** wherein the symptomatic cold reliever comprises an active agent selected from the group consisting of oil of wintergreen, menthol, thymol, camphor, oil of peppermint, eucalyptus oil, phenylephrine hydrochloride, pheniramine maleate, benzalkonium chloride, methyl salicylate, pseudoephedrine hydrochloride, oxymetazoline hydrochloride, xylometazoline hydrochloride, methazoline hydrochloride, epinephrine, spirits of turpentine, ephedra (ma huang), coltsfoot (*Tussilago farfara L.*), ginger (*Zingiber officinale*), and naphazoline hydrochloride.

17. The skin patch of claim **14** wherein the symptomatic cold reliever is dispersed in a vehicle including a thickener

comprising a natural or synthetic gel-forming polymer selected from the group consisting of gum karaya, gum acacia, locust bean gum, guar gum, modified guar gum, maltodextrin, carboxymethyl cellulose, carboxypropyl cellulose, polyacrylamide, polyacrylic acid, a natural or synthetic rubber, a petroleum derivative, and a resin.

18. The skin patch of claim **14** wherein the symptomatic cold reliever is dispersed in a vehicle that includes a resin emulsion adhesive.

19. The skin patch of claim **14** wherein the symptomatic cold reliever is dispersed in a vehicle including an emulsion adhesive comprising a member selected from the group consisting of acrylate emulsion adhesive, an acrylic ester copolymer, a vinyl acetate resin, a copolymer of vinyl acetate and dioctyl maleate, and silicone adhesive.

20. The skin patch of claim **17** wherein the symptomatic cold reliever is contained in a vehicle that includes a humectant comprising a polyhydric alcohol.

21. A method of reducing or alleviating one or more of the symptoms of cough due to colds, minor throat and bronchial imtation, nasal or chest congestion, comprising,

providing a flexible foraminous carrier,

supporting a symptomatic cold reliever upon the foraminous carrier, and

providing instructions for bonding the foraminous carrier to the skin surface in sufficient proximity to the nose or mouth to enable the symptomatic cold reliever to be available for natural inhalation during respiration through the nose or mouth wherein the skin patch is free of a 5-substained furan methyl ketone.

22. The method of claim **21** wherein the symptomatic cold reliever is an ointment-containing an active agent selected from the group consisting of oil of wintergreen, menthol, thymol, camphor, oil of peppermint, eucalyptus oil, phenylephrine hydrochloride, pheniramine maleate, benzalkonium chloride, methyl salicylate, pseudoephedrine hydrochloride, oxymetazoline hydrochloride, xylometazoline hydrochloride, methazoline hydrochloride, epinephrine, spirits of turpentine, ephedra (ma huang), coltsfoot (*Tussilago farfara L.*), ginger (*Zingiber officinale*), and naphazoline hydrochloride.

23. The method of claim **21** wherein the symptomatic cold reliever is dispersed in a vehicle which includes a thickener comprising a natural or synthetic polymer.

24. The method of claim **23** wherein the polymer comprises a member selected from the group consisting of karaya gum, gum acacia, locust bean gum, guar gum, modified guar gum, maltodextrin, carboxymethyl cellulose, carboxypropyl cellulose, polyacrylamide, and polyacrylic acid.

25. The method of claim **21** wherein the foraminous carrier is bonded to the skin by a non-irritating medical grade, pressure-sensitive adhesive connected to the carrier.

26. The method of claim **25** wherein the pressure-sensitive adhesive comprises a member selected from the group consisting of acrylate emulsion adhesive, an acrylic ester copolymer, a vinyl acetate resin, a copolymer of vinyl acetate and dioctyl maleate, silicone adhesive, natural or synthetic rubber, a petroleum derivative, and a resin.

27. The method of claim **21** wherein the instructions direct one to apply the foraminous carrier to the nasolabial area beneath the nose.

28. The method of claim **21** wherein the instructions direct one to apply the foraminous carrier to the chin.

29. The method of claim **21** wherein the instructions direct one to apply the foraminous carrier to the chest.

30. The method of claim **21** wherein the instructions direct one to apply the foraminous carrier to the throat.

31. The skin patch of claim **7** wherein the skin patch provides a dual therapeutic action including vapor inhalation of the symptomatic cold reliever and dermal absorption of said symptomatic cold reliever into the skin and the underlying tissue.

32. The skin patch of claim **1** wherein the foraminous carrier is a perforated plastic film.

33. The skin patch of claim **31** wherein the symptomatic cold reliever is absorbed into the skin and underlying tissue.

34. The skin patch of claim **31** wherein the ointment contains an analgesic and the symptomatic cold reliever absorbed into the skin and underlying tissue is said analgesic.

35. A skin patch for the relief of the symptoms of cough, colds, nasal congestion or chest congestion, comprising,

a symptomatic cold reliever supported upon a flexible foraminous carrier and means operatively associated with the carrier for securing the carrier to the skin surface to enable the symptomatic cold reliever to be available for natural inhalation during respiration through the mouth or nose;

wherein the symptomatic cold reliever is dispersed in a vehicle that includes a resin emulsion adhesive wherein the skin patch is free of a 5-substituted furan methyl ketone.

36. A skin patch for the relief of the symptoms of cough, colds, nasal congestion or chest congestion, comprising,

a symptomatic cold reliever supported upon a flexible foraminous carrier and means operatively associated with the carrier for securing the carrier to the skin surface to enable the symptomatic cold reliever to be available for natural inhalation during respiration through the mouth or nose;

wherein the means comprises an adhesive selected from the group consisting of acrylate emulsion adhesive, an acrylic ester copolymer, a vinyl acetate resin, a copolymer of vinyl acetate and dioctyl maleate, silicone adhesive, natural or synthetic rubber, a petroleum derivative, and a resin wherein the skin patch is free of a 5-substituted furan methyl ketone.

37. A skin patch for the relief of the symptoms of cough, colds, nasal congestion or chest congestion, comprising,

a symptomatic cold reliever supported upon a flexible foraminous carrier and means operatively associated with the carrier for securing the carrier to the skin surface to enable the symptomatic cold reliever to be available for natural inhalation during respiration through the mouth or nose;

wherein the symptomatic cold reliever is dispersed in an ointment including as a thickener a natural or synthetic gel-forming polymer comprising a member selected from the group consisting of gum karaya, gum acacia, locust bean gum, guar gum, modified guar gum, maltodextrin, carboxymethyl cellulose, carboxypropyl cellulose, polyacrylamide, and polyacrylic acid; and

wherein the symptomatic cold reliever is dispersed in a vehicle which includes a humectant comprising a polyhydric alcohol wherein the skin patch is free of a 5-substituted furan methyl ketone.

38. The skin patch of claim **1** wherein the symptomatic cold reliever is a cough suppressant.

39. The skin patch of claim **38** wherein the cough suppressant is a topical antitussive.

40. The skin patch of claim **39** wherein the topical antitussive is camphor or menthol.

41. The skin patch of claim **7** wherein the skin patch provides a therapeutic action including vapor inhalation of the symptomatic cold reliever.

* * * * *

EXHIBIT I

US006844005B2

(12) **United States Patent**
Wahi et al.

(10) **Patent No.: US 6,844,005 B2**
(45) **Date of Patent: Jan. 18, 2005**

(54) **ELECTROSTATICALLY CHARGED NASAL APPLICATION PRODUCT WITH INCREASED STRENGTH**

(75) Inventors: **Ashok L. Wahi**, Hillsborough, NJ (US); **Kanneth Sugathan**, Franklin Park, NJ (US)

(73) Assignee: **Trutek Corp**, Hillsborough, NJ (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 370 days.

(21) Appl. No.: **10/082,978**

(22) Filed: **Feb. 25, 2002**

(65) **Prior Publication Data**

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(51) **Int. Cl.**[7] **A61F 13/02**; A61K 9/14

(52) **U.S. Cl.** **424/434**; 424/443; 424/484; 424/485; 424/486

(58) **Field of Search** 424/434, 443, 424/484, 485, 486, 43

(56) **References Cited**

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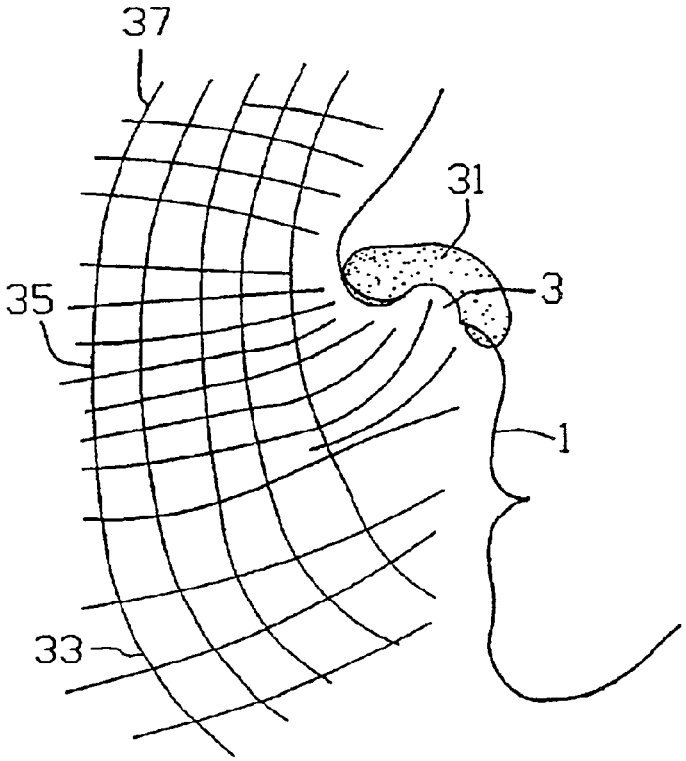
Primary Examiner—Carlos A. Azpuru
(74) *Attorney, Agent, or Firm*—Kenneth P. Glynn, Esq.

(57) **ABSTRACT**

The present invention relates to a nasal topical application product for restricting the flow of airborne contaminants into a human nasal passage by creation of a proximate, enhanced electrostatic field. This nasal application product includes: (a) a plurality of masses of one or more electrostatic polymers; and, (b) a topical carrier having the plurality of masses dispersed through a portion thereof. At least one of the electrostatic polymers is a poly (dimethyl diallyl ammonium chloride) polymer and is included in the product in an amount of at least 10% by weight, based on the total weight of the polymers and the topical carrier. The nasal application product may be topical solutions, semisolids, spray solutions and vaporizable solutions. Topical applications may be in the form of ointments, pastes, creams and gels. The carrier of the nasal application product of the present invention may be selected from the group consisting of dilutents, volatile spray carriers, lotions, solvents, gels and hydrogels. In some embodiments, substrates, e.g., bandage type substrates, with adhesive on one side and the product polymer(s) and carrier on the opposite side, may be employed.

20 Claims, 2 Drawing Sheets



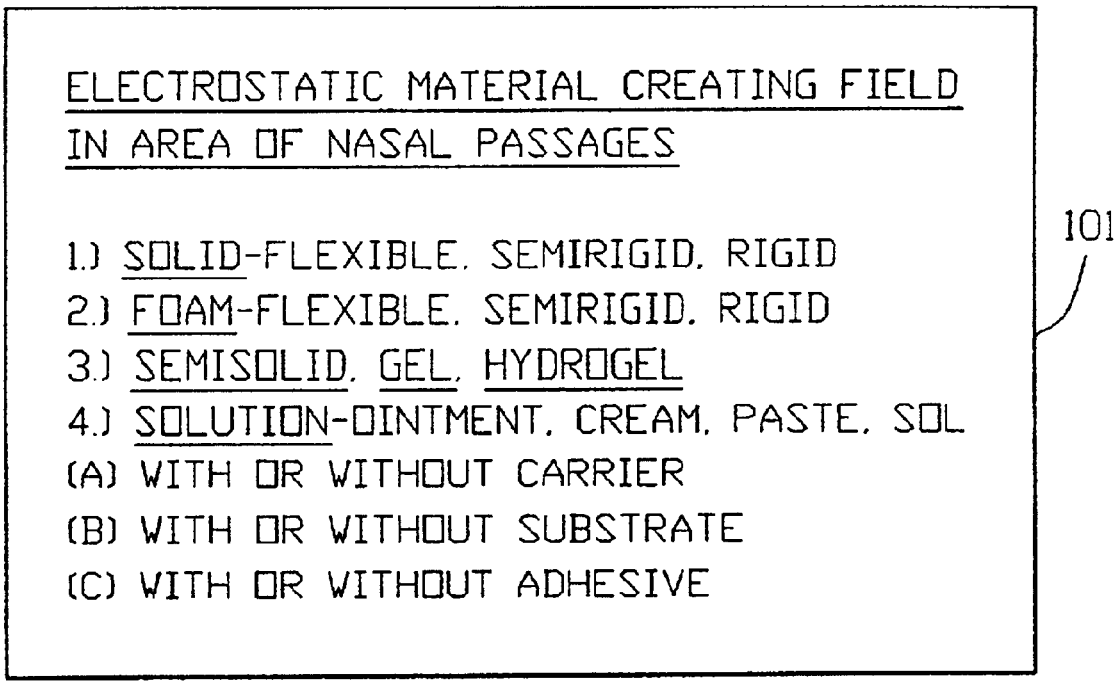

ELECTROSTATIC MATERIAL CREATING FIELD
IN AREA OF NASAL PASSAGES
1.) SOLID-FLEXIBLE, SEMIRIGID, RIGID
2.) FOAM-FLEXIBLE, SEMIRIGID, RIGID
3.) SEMISOLID, GEL, HYDROGEL
4.) SOLUTION-OINTMENT, CREAM, PASTE, SOL
(A) WITH OR WITHOUT CARRIER
(B) WITH OR WITHOUT SUBSTRATE
(C) WITH OR WITHOUT ADHESIVE
101

FIG. 1

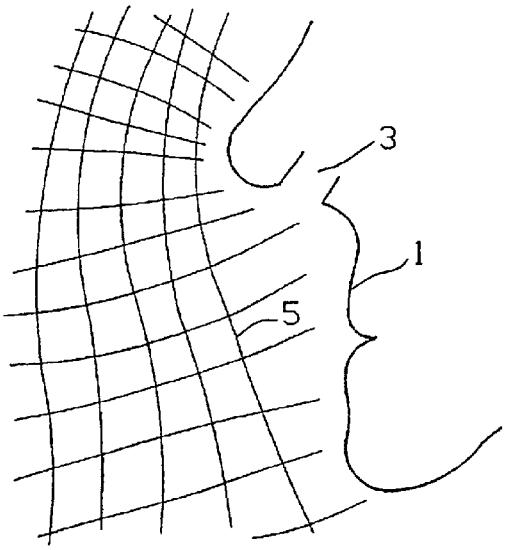


FIG. 2

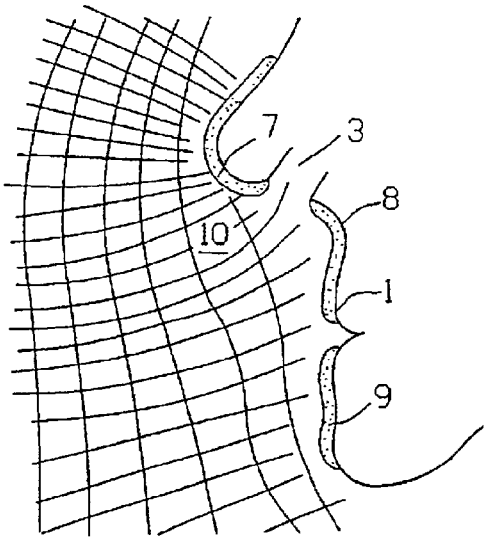


FIG. 3

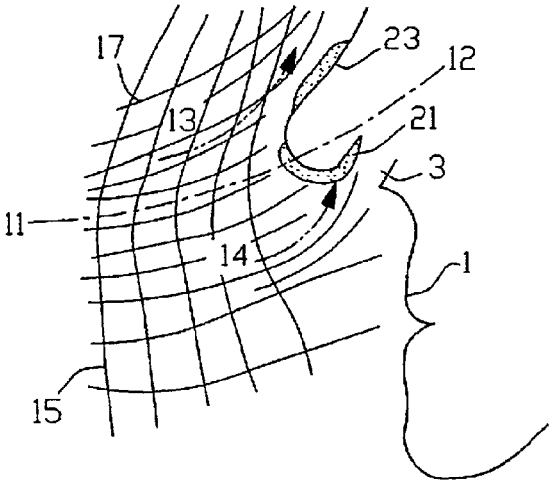


FIG. 4

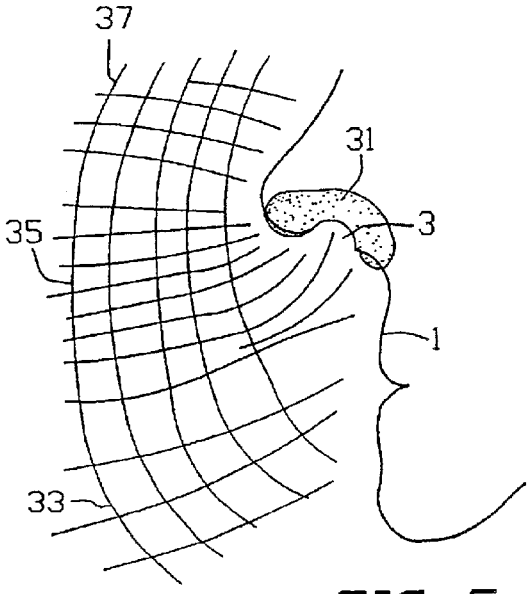


FIG. 5

ELECTROSTATICALLY CHARGED NASAL APPLICATION PRODUCT WITH INCREASED STRENGTH

REFERENCE TO RELATED CASES

The present invention relates to electrostatically charged topical nasal application products which have been developed and improved since their original development as set forth in two previously issued United States patents. For this reason, the entire specification and claims are incorporated herein in their entirety by reference, as to U.S. Pat. No. 5,468,488, entitled "ELECTROSTATICALLY CHARGED NASAL APPLICATION PRODUCT AND METHOD" issued to Ashok L. Wahi, inventor, on Nov. 21, 1995, and U.S. Pat. No. 5,674,481, entitled "ELECTROSTATICALLY CHARGED NASAL APPLICATION PRODUCT" ISSUED TO Ashok L. Wahi on Oct. 7, 1997.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to products for restricting the flow of airborne contaminants into a nasal passage by creating an electrostatic field of increased charge in an area about the nasal passage. This prevents or reduces the inflow of airborne contaminants to the nasal passage.

2. Information Disclosure Statement

U.S. Pat. No. 5,468,488 describes a method for restricting the flow of airborne contaminants into a nasal passage. It involves creating an electrostatic field in an area near a human nasal passage. The electrostatic field may either repel or attract airborne contaminants or both. The method involves applying a topical application having a plurality of masses of one or more electrostatic materials, and a carrier having the plurality of masses dispersed therein. The masses have an average cross sectional area of about one square millimeter to about 50,000 square millimeters, and are of sufficient charge to create an electrostatic field which will prevent at least some airborne contaminants from passing into a human nasal passage. The topical application may be in the form of a solution, a semisolid, a solid, a spray solution or a vaporizable solution.

U.S. Pat. No. 5,674,481 describes a product and method for restricting the flow of airborne contaminants into a nasal passage. It involves creating an electrostatic field in an area near a nasal passage. The electrostatic field may either repel or attract airborne contaminants or both. The product may take the form of a plurality of masses of one or more electrostatic materials, the masses have an average cross sectional area of about one square millimeter to about 50,000 square millimeters, the mass being of sufficient charge to create an electrostatic field which will prevent at least some airborne contaminants from passing into a nasal passage. There is also a carrier material with the plurality of masses dispersed therein. The product may be a topical solution, a semi solid, a solid, a spray solution or a vaporizable solution. Alternatively, it may be in a form which includes a substance for the carrier and, in one preferred embodiment, the substrate would be an adhesive material such as a bandage.

The aforesaid references describe various methods and products for restricting airborne contaminant flow to the nasal passage area utilizing the suggested formulae described therein. It has now been discovered that utilization of at least 10% of one specific active electrostatically charged polymer provides significantly increased charge density and efficacy as compared to other electrostatic polymers at lower, the same or higher concentrations than the present invention levels of the poly (dimethyl diallyl ammonium chloride). For this reason, notwithstanding the prior art, the present invention is neither taught nor rendered obvious thereby.

SUMMARY OF THE INVENTION

The present invention relates to a nasal topical application product for restricting the flow of airborne contaminants into a human nasal passage by creation of an artificial electrostatic field near the human nose This nasal application product includes: (a) a plurality of masses of one or more electrostatic polymers; and, (b) a topical carrier having the plurality of masses dispersed through a portion thereof. In the present invention, at least one of the electrostatic polymers is a poly (dimethyl diallyl ammonium chloride) polymer and is included in the product in an amount of at least 10% by weight, based on the total weight of the plurality of masses of one or more electrostatic polymers and the topical carrier.

The nasal application product of the present invention may be selected from the group consisting of topical solutions, semisolids, spray solutions and vaporizable solutions. Topical applications may be in the form of ointments, pastes, creams and gels.

The carrier of the nasal application product of the present invention may be selected from the group consisting of diluents, volatile spray carriers, lotions, solvents, gels and hydrogels. When the carrier is a dilutent, it may be selected from the group consisting of glycols, glycerines, organic surfactants, esters being of unsaturated fatty acids, and mixture thereof. When the carrier is a volatile spray carrier, it may be selected from the group consisting of water, natural oils, glycols, organic surfactants and mixtures thereof. When the carrier is a lotion, it may be selected from the group consisting of polyethylene glycols, natural oils, silicones, homogenizers, and mixtures thereof. When the carrier is a gel, it may be selected from the group consisting of three dimensional polymeric matrices of natural polymers, synthetic polymers, copolymers, and mixtures thereof

In some preferred embodiments of the nasal application product of the present invention, the carrier includes at least one homogenizer and at least one glycol polymer.

In preferred some embodiments of the present invention nasal application product, the carrier includes about 1 to about 5% by weight of a glycol compound and about 60 to 85% by weight of water, based on the total weight of the plurality of masses of one or more electrostatic polymers and the topical carrier. Preferred nasal application product topical carrier formulae include:

(a) about 1% to about 5% by weight of a glycol compound selected from the group consisting of polyethylene glycol, polypropylene glycol and mixtures thereof;

(b) about 60% to about 85% by weight of water; and,

(c) about 0% to about 2.5% of one or more stearate compounds;

all of the above weight percentages being based on the total weight of the plurality of masses of one or more electrostatic polymers and the topical carrier.

The present invention nasal application products may further include a substrate containing the topical carrier with a plurality of masses of one or more electrostatic polymers dispersed through at least a portion thereof. The substrate may be a flexible substrate, such as a cloth or other woven

material or a synthetic sheet material with an adhesive thereon, e.g., a bandage type of substrate.

BRIEF DESCRIPTION OF THE DRAWINGS

The present invention should be more fully understood when the specification herein is taken in conjunction with the drawings appended hereto wherein:

FIG. **1** shows a schematically the product concept of the present invention;

FIG. **2** shows a side partial stylized view of a human illustrating a typical electrostatic field around a human nasal passage;

FIG. **3** shows the same stylized human outline as in FIG. **2** but with an artificially created electrostatic field near a persons nose to restrict the flow of airborne contaminants into the nasal passages;

FIG. **4** shows another alternative present invention embodiment wherein a combination of artificially created electrostatic fields are shown; and,

FIG. **5** shows a mild artificially created electrostatic field.

DETAILED DESCRIPTION OF THE PRESENT INVENTION

The FIGS. **1** through **5** are briefly described above and are identical to the drawings set forth in the two issued patents incorporated by reference stated above. As such, the detailed explanation and description set forth therein is incorporated herein and, thus, not unnecessarily repeated here.

The present invention is based on the surprising and unexpected discovery that a significant increase in electrostatic charge density is achieved with the present invention by use of at least 10% by weight of poly (dimethyl diallyl ammonium chloride). This is contrary to experiences of the inventors wherein increase in the active (electrostatic polymer) after a level achieved at less than 8% or so, did not significantly increase the electrostatic charge density. However, in the case of the present invention, a charge density increase of about 20% to 25% was realized.

The following examples are representative of the present invention:

EXAMPLE #1

Ingredient	% age composition by weight
1. Deionized Water	75.9
2. Potassium Sorbate	0.1
3. Celquat SC 240 C	3.9
4. Polawax 5% in water	4.9
5. Agequat 400	12.9
6. Arlacel 165	1.0
7. Tween 60	0.1
8. Propylene Glycol	1.2
	100.0

EXAMPLE #2

Ingredient	% age composition
1. Deionized water	73.5
2. Celquat SC 240 C	3.8
3. Agequat 400	12.6
4. Polawax 5% in water	9.5
5. Potassium Sorbate	0.1
6. Necon LO	0.5
	100.0

EXAMPLE #3

1. Deionized water	84.9
2. Celquat SC 240 C	4.0
3. Agequat 400	11.0
4. Potassium Sorbate	0.1
	100.0

Generic/Chemical name of the above ingredients are:
Celquat SC 240 C; Quarternary Cellulosic Derivative
Polawax; Fatty Alcohol, Polysorbate Blend
Agequat 400; Poly(Dimethyl Diallyl Ammonium Chloride)
Arlacel 165; Glycerol Monostearate and Polyethylene Stearate
Necon LO; A surfactant
Tween 60; Polysorbate
Propylene Glycol; 1,2-Propane Diol

Celquat SC 240C is a polyquatermary animonium cellulose manufac ed by National Starch and Chemical Company (New Jersey). Necon LO is dimethy lauramine oleate manufactured by Aizo Inc. (A New Jersey Corporation). Arlacel 165 is a 50/50 mixture of glyscerol monosterate and polyoxyethylene stearate manufactured by Uniqema Corp.

Brief Process of Formulation:

In all of the above Examples, the ingredients are added one by one, at room temperature, in the order listed to water, while stirring. No new ingredient is added until the one added before was dispersed completely. Polawax and Arlacel were dispersed by warming the mixture, to 60 degrees C., over a water bath. After all the ingredients were added, the contents were mixed well for uniformity, let cool to room temperature and bottled.

EXAMPLE #4

Ingredient	Weight (Kg/15 Kg)	% w/w
1. Polawax (5% dispersion)	0.7500	5.00
2. Propylene Glycol	0.3000	2.00
3. Celquat SC-240C	0.6000	4.00
4. Agequat 400	1.6500	11.00
5. Methylparaben	0.0300	0.20
6. Propylparaben	0.0150	0.10
7. Tetrasodium Edetate	0.0075	0.05
8. Arlacel 165	0.1500	1.00
9. Tween 60	0.0150	0.10
10. Gerinall-II	0.0450	0.30
11. Water	11.4375	76.25
TOTAL	15.0000	100.00

Prodedure:

In a suitable container prepare a 5% dispersion of Polawax in water by mixing 37.5 g in 750 g of water previously heated at 70 plus of minus 5 degrees C. (Step A)

In a tared stainless steel container with 10 Kg of water previously heated at 70 plus of minus 5 degree C. and stirred mechanically, add Celquat SC-240C gradually, directly into the vortex. Make sure no clumps are formed. As the dispersion thickens, increase the speed of the mixer enough to maintain the movement of the surface and the bulk of the dispersion. Allow mixing for one to one and a half hour to get a clear, uniform, transparent dispersion at 70 degrees C. Add sequentially Tetrasodium Edetate, Arlacel 165, Tween 60 and Agequat 400 with mixing, making sure that each ingredient is completely dissolved or dispersed before adding the next one. (Step B)

Add dispersion in step A to the dispersion in step B with continued mixing. Allow the mixture to cool down gradually to about 50 degrees C. (Step C)

In a suitable container dissolve Methylparaben, Propylparaben and Germall-II in Propylene Glycol and heat. (Step D)

When the temperature of the mixture from step D reaches 50 degrees C. add solution in step C with continued mixing. (Step E)

Dilute the combined mixture from step E to 15.0 Kg by adding Water previously heated at 50 degrees C. and continue mixing.

Allow the product to cool to 30 degrees C. to form a gel.

Transfer the bulk gel to suitable polyethylene lined containers.

Comparative tests of electrostatic charge density revealed an increase of 20% to 25% as compared to prior art formulations and as compared to other formulations having over 10% electrostatic polymer using actives other than poly (dimethyl diallyl ammonium chloride).

Obviously, numerous modifications and variations of the present invention are possible in light of the above suggestions. It is therefore understood that within the scope of the appended claims, the invention may be practiced otherwise than as specifically described herein.

What is claimed is:

1. A nasal topical application product for restricting the flow of airborne contaminants into a human nasal passage by creation of an artificial electrostatic field near the human nose, wherein the nasal application product consists essentially of:

(a) a plurality of masses of one or more electrostatic polymers; and,

(b) a topical carrier having said plurality of masses dispersed through a portion thereof;

wherein at least one of said one or more electrostatic polymers is a poly (dimethyl diallyl ammonium chloride) polymer and is included in said product in an amount of at least 10% by weight, based on the total weight of said plurality of masses of one or more electrostatic polymers and said topical carrier.

2. The nasal application product of claim **1** wherein said product is selected from the group consisting of topical solutions, semisolids, spray solutions and vaporizable solutions.

3. The nasal application product of claim **1** wherein said product is selected from the group consisting of ointments, pastes, creams and gels.

4. The nasal application product of claim **1** wherein said carrier is selected from the group consisting of diluents, volatile spray carriers, lotions, solvents, gels and hydrogels.

5. The nasal application product of claim **1** wherein said carrier is a dilutent selected from the group consisting of alcohols, glycerines, organic surfactants, esters being of unsaturated fatty acids, and mixture thereof.

6. The nasal application product of claim **4** wherein said carrier is a volatile spray carrier selected from the group consisting of water, natural oils, glycols, organic surfactants and mixtures thereof.

7. The nasal application product of claim **4** wherein said carrier is a lotion selected from the group consisting of polyethylene glycols, natural oils, silicones, homogenizers, and mixtures thereof.

8. The nasal application product of claim **4** wherein said carrier is a gel selected from the group consisting of three dimensional polymeric matrices of natural polymers, synthetic polymers, copolymers, and mixtures thereof.

9. The nasal application product of claim **1** wherein said carrier includes at least one honogenizer and at least one glycol polymer.

10. The nasal application product of claim **9** wherein said carrier includes about 1 to about 5% by weight of a glycol compound and about 60 to 85% by weight of water, based on the total weight of said plurality of masses of one or more electrostatic polymers and said topical carrier.

11. The nasal application product of claim **10** wherein said topical carrier includes:

(a.) about 1% to about 5% by weight of a glycol compound selected from the group consisting of polyethylene glycol, polypropylene glycol and mixtures thereof;

(b.) about 60% to about 85% by weight of water; and,

(c.) about 0% to about 2.5% of one or more stearate compounds;

all of the above weight percentages being based on the total weight of said plurality of masses of one or more electrostatic polymers and said topical carrier.

12. The nasal application product of claim **1** wherein said product further includes a substrate containing said carrier with said plurality of masses of one or more electrostatic polymers dispersed through a portion thereof.

13. The nasal application product of claim **11** wherein said substrate is a flexible substrate having an adhesive thereof.

14. The nasal application product of claim **11** wherein said substrate is a bandage.

15. The nasal application product of claim **12** wherein the nasal application product of claim **1** wherein said carrier includes at least one homogenizer and at least one glycol polymer.

16. The nasal application product of claim **15** wherein the nasal application product of claim **9** wherein said carrier includes about 1 to about 5% by weight of a glycol compound and about 60 to 85% by weight of water, based on the total weight of said plurality of masses of one or more electrostatic polymers and said topical carrier.

17. The nasal application product of claim **16** wherein said topical carrier includes:

a. about 1% to about 5% by weight of a glycol compound selected from the group consisting of polyethylene glycol, polypropylene glycol and mixtures thereof;

b. about 60% to about 85% by weight of water; and,

c. about 0% to about 2.5% of one or more stearate compounds;

all of the above weight percentages being based on the total weight of said plurality of masses of one or more electrostatic polymers and said topical carrier.

18. The nasal application product of claim **13** wherein said carrier includes at least one homogenizer and at least one glycol polymer.

19. The nasal application product of claim **18** wherein said carrier includes about 60 to 85% by weight of water, based on the total weight of said plurality of masses of one or more electrostatic polymers and said topical carrier.

20. The nasal application product of claim **19** wherein said topical carrier includes:

a. about 1% to about 5% by weight of a glycol compound selected from the group consisting of polyethylene glycol, polypropylene glycol and mixtures thereof;

b. about 60% to about 85% by weight of water; and,

c. about 0% to about 2.5% of one or more stearate compounds;

all of the above weight percentages being based on the total weight of said plurality of masses of one or more electrostatic polymers and said topical carrier.

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